

# **EVIDENCE REPORT AND EVIDENCE-BASED RECOMMENDATIONS:**

## **Interventions to Promote Smoking Cessation in the Medicare Population**



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## **Preface**

The Health Care Financing Administration (HCFA), in consultation with other Agencies in the Department of Health and Human Services, initiated the Healthy Aging Project to enhance and promote the health of older people. A major objective of the Healthy Aging Project is to identify, synthesize and disseminate evidence and expert opinion on health promotion and disease prevention interventions that are evidence-based. HCFA is sponsoring reports that present evidence and expert opinion to assist public and private sector organizations in their efforts to improve the delivery of Medicare-covered preventive benefits and promote behavioral risk factor reduction. These reports provide comprehensive, science-based information on effective and cost-effective interventions targeting the senior population. RAND is producing these reports under a HCFA contract.

HCFA expects that these evidence reports will inform peer review organizations, individual health plans, providers and purchasers, including Medicare and Medicaid, as well as the health care system as a whole by providing important information to help improve the delivery and quality of preventive health care for older people.

We welcome written comments on this evidence report. They may be sent to:

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## **The Southern California Evidence-Based Practice Center**

The Southern California Evidence-Based Practice Center is part of the Evidence-Based Practice Program sponsored by the Agency for Health Care Policy and Research. One of 12 such Centers nationwide, the Center conducts systematic reviews and technology assessments of all aspects of health care; performs research on improving the methods of synthesizing the scientific evidence and developing evidence reports and technology assessments; and provides technical assistance to other organizations in their efforts to translate evidence reports and technology assessments into guidelines, performance measures, and other quality-improvement tools.

The Center combines the talents of RAND and its five affiliated regional health care institutions: the University of California, Los Angeles; the University of California, San Diego; Cedars-Sinai Medical Center; the University of Southern California; and Value Health Sciences. In addition, through the VA/RAND/ University of California Field Program "Center for the Study of Health Care Provider Behavior," four Department of Veterans Affairs facilities collaborate with the Center. The Center is also affiliated with five health services research training programs.

The Southern California Center is the natural outcome of more than 20 years of work by RAND and its affiliated institutions in reviewing the biomedical literature for evidence of benefits, harms, and costs; using meta-analysis, decision analysis, and cost-effectiveness analysis to synthesize the literature; developing measures of clinical appropriateness and practice guidelines; developing and assessing medical review criteria; and developing and assessing performance measures and other tools for translating evidence-based knowledge into clinical practice. The hallmark of this work has been (a) its multi-disciplinary nature: RAND and its affiliated institutions combine the talents of clinicians, health services researchers, epidemiologists, statisticians, economists, and advanced methods experts in meta-analysis and decision analysis; (b) the advancement of knowledge about the methods for performing literature reviews, synthesizing evidence, and developing practice guidelines or review criteria; and (c) the emphasis on developing and evaluating products for use in the real world of health care delivery.

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## **EXECUTIVE SUMMARY**

### **INTRODUCTION**

Smoking is the single most preventable cause of morbidity and mortality in the United States. Smoking is a major risk factor for cardiovascular disease, chronic obstructive pulmonary disease, cancer, hypertension, diabetic complications and osteoporosis.<sup>1, 2</sup> Tobacco use causes more than 430,000 deaths, and costs the United States between \$50 and \$73 billion in medical expenses each year.<sup>3, 4</sup>

In 1995, 47 million U.S. adults 18 years of age and older reported that they were current smokers. Approximately 70% of current smokers expressed their desire to quit smoking completely, while almost 46% reported they had stopped smoking for at least one day in the preceding 12 months.<sup>5</sup>

Approximately 13% of people 65 and older reported that they were smokers in 1995.<sup>5</sup> Today's older smokers grew up in an era in which advertisers, even physicians, promoted smoking; the adverse effects of smoking had not yet been established. The consequences of smoking among this cohort are now evident. In 1990, smoking caused over 287,000 deaths in the U.S. among persons age 65 and older--about 70% of the U.S. smoking-related deaths that year.<sup>6</sup>

Zhang and colleagues estimated that smoking-related illnesses accounted for about \$14.2 billion in Medicare expenditures in 1993, about 9.4% of Medicare's total budget. More specifically, smoking accounted for 11.4% of hospital care, 11.3% of nursing home care, 5.9% of home health care, and 5.6% of ambulatory care.<sup>7</sup> It is estimated that between 1995 and 2015, tobacco-related diseases will cost Medicare about \$800 billion.<sup>8</sup>

There are significant benefits to smoking cessation, even after 30 or more years of regular smoking.<sup>9</sup> Data from the Established Population for the Epidemiological Study of Elderly (EPESE) indicate that smokers who quit have cardiovascular mortality rates similar to those of nonsmokers, and that this benefit is unrelated to age or the time elapsed since cessation.<sup>10</sup> In one study, older smokers who already had coronary artery disease improved their survival and risk of heart attack by quitting.<sup>11</sup> In addition, lung function and circulation begin to improve immediately after cessation.<sup>12</sup> A person who smokes more than 20 cigarettes per day and who quits at age 65 can expect to increase his or her life expectancy by 2 to 3 years.<sup>13</sup> Quitting smoking also greatly increases the quality of life for older adults.

Unfortunately, older smokers may be less likely to perceive the health consequences of smoking. For example, according to a recent survey of members of the American Association of Retired Persons (AARP), 47% of smokers age 50 and over did not believe that quitting could improve their health. In addition, 45% did not believe that continuing to smoke could further damage their health.<sup>14</sup> Still, older smokers are more likely to achieve success in their cessation attempts than younger smokers are.<sup>15, 16</sup> Thus, although special emphasis needs to be applied in addressing the barriers to quitting among the elderly, age is not a significant obstacle to cessation interventions.

A number of interventions to improve smoking cessation have been studied, and many of these are recommended in clinical practice guidelines promulgated by various organizations.<sup>17</sup> To better understand such interventions in the Medicare population, the Health Care Financing Administration (HCFA), as part of its Healthy Aging project, commissioned an evidence-based systematic review of smoking cessation, the results of which are detailed in this report.



## **METHODS**

We employed the evidence review and synthesis methods of the Southern California Evidence Based Practice Center, an Agency for Healthcare Research and Quality designated center for the systematic review of literature on the evidence on benefits and harms of health care interventions. Our literature review process consisted of the following steps:

- Develop a conceptual model.
- Identify sources of evidence (in this case, sources of scientific literature).
- Identify potential evidence.
- Evaluate potential evidence for methodological quality and relevance.
- Extract study-level variables and results from studies meeting methodological and clinical criteria.
- Synthesize the results.

The interventions used to promote smoking cessation among persons age 65 or older fell into the following broad categories: self-help, counseling, pharmacotherapy, education, financial incentives (provider and patient), regulatory and legislative interventions, and media campaigns. We used several sources to identify existing research and potentially relevant evidence, including the Cochrane Collaboration Tobacco Group database, the draft Public Health Service (PHS) clinical practice guideline,<sup>18</sup> ten previously completed systematic reviews, and a library search of the computerized databases Medline, PsychLit, Dissertation Abstracts, Applied Social Sciences Index, and Social Science Citations Index.

While we were primarily searching for data relevant to the Medicare population, we included studies on adult populations under age 65 to avoid loss of potentially useful data. To be accepted as evidence, a study had to measure quit rates at least five months from the start of an

intervention and use one of the following designs: randomized controlled trial, controlled clinical trial, controlled before and after study, or interrupted time series with adequate data points. From these articles we abstracted data such as the number and characteristics of patients; setting, location, and target of the intervention; intensity of the intervention; types of outcome measures; time from intervention until outcome measurement; and results. In the analysis itself, we sought to answer the following questions specified by HCFA:

1. If Medicare were to offer a smoking cessation benefit, how would providers be reimbursed? For example, by minutes of counseling?
2. How useful is provider training?
3. How should provider compliance be measured and monitored?
4. What means could be used to curb overutilization? Cost sharing by patients? Annual caps on services?
5. How effective are patient financial incentives?
6. How effective is telephone counseling?
7. How effective is other counseling?
8. How effective is pharmacotherapy?
9. How effective is self-help?
10. Which practice settings are most effective? Outpatient? Hospital? Free-standing smoking cessation clinics?
11. Who is most effective at delivering smoking cessation interventions? Physicians? Psychologists? Nurses? Dentists?
12. Do certain interventions work better for special populations?
13. What are costs of interventions?
14. Which interventions are most cost-effective?

Some of these questions were similar or even identical to questions being assessed by the team developing the Public Health Service Report Treating Tobacco Use and Dependence: A Clinical Practice Guideline.<sup>18</sup> However, the focus of this HCFA report was to draw inferences for

Medicare programs and policies for an insurance benefit. With the permission of the principal investigator of the Public Health Service project, we present their analyses where applicable. A panel of experts was convened on October 21, 1999; feedback from the panel was useful in fine-tuning our analysis and recommendations.

## **RESULTS**

Our search yielded 488 articles, 248 of which met our screening criteria. The type of intervention examined in the greatest number of studies, 149, was patient education; we found 118 studies that used individual counseling, 104 studies that used self-help, and 76 studies that used patient financial incentives. (These categories are not mutually exclusive.) Of the 248 selected studies, 40 were randomized or controlled clinical trials.

There were no studies comparing smoking cessation outcomes as a function of different reimbursement schemes (Question 1) or addressing the issue of provider compliance and monitoring (Question 3).

### QUESTION 2. HOW USEFUL IS PROVIDER TRAINING?

A recent meta-analysis<sup>19</sup> of nine studies provided data on the effect of provider education on both provider performance and patient smoking cessation rates. Eight of the studies reported the effect of training medical practitioners, while one reported the effect of training dental practitioners. The provider training in all studies was conducted on a group basis, in either a tutorial or a workshop format. The analysis showed that trained providers were significantly more likely to perform smoking-cessation tasks than untrained providers. Patient outcomes were also affected: Patients who saw trained providers were more likely to stop smoking than those who saw untrained providers (pooled odds ratio=1.48, 95% C.I.=1.20 to 1.83).

QUESTION 4 & 5. WHAT MEANS CAN BE USED TO CURB OVERUTILIZATION? HOW EFFECTIVE ARE PATIENT FINANCIAL INCENTIVES?

We found one article that reported on the effectiveness and cost-effectiveness of different levels of coverage for both a behavior modification benefit and a nicotine replacement benefit for smoking cessation. This study was performed at a health maintenance organization (HMO) in the Pacific Northwest and involved over 90,000 patients.<sup>20</sup> The four benefit strategies are shown in the table below.

**Cost-Sharing Plans Analyzed**

Plan	Behavior Benefit	Nicotine Replacement Benefit	Cost/Quitter
Full	100%	100%	\$1171
Standard	50%	100%	\$797
Flipped	100%	50%	\$870
Reduced	50%	50%	\$801

The most cost-effective benefit plans (from the health plan perspective) were those in which the patients bore some financial responsibility for the smoking cessation program. However, full coverage of both benefits resulted in more quitters (approximately two to four times as many quitters in the full benefit plan as in the reduced coverage plans).

We found no studies that specifically addressed curbing overutilization or the effect of capitation limits on services. Our expert panel emphasized that overutilization should not be a problem, and that we should concentrate on convincing smokers to engage in cessation interventions.

## QUESTION 6 & 7. HOW EFFECTIVE IS COUNSELING?

A number of systematic reviews have examined the effectiveness of counseling for smoking cessation.<sup>17, 18, 21-23</sup> Preliminary results from the 2000 Public Health Service clinical practice guideline<sup>18</sup> show that all forms of counseling are statistically significantly effective at promoting smoking cessation. In the analysis, individual counseling yielded the highest adjusted odds ratio for success, followed by group counseling, phone counseling, and self help. Individual counseling was statistically significantly superior to self-help (which itself was only marginally statistically different than control). The greater effectiveness of individual counseling over telephone counseling approached statistical significance. There was no statistically significant difference in effectiveness between group counseling and telephone counseling. In another quantitative systematic review that examined only physician counseling,<sup>24</sup> 16 trials reported the effect of brief advice on smoking cessation. These trials had a pooled odds ratio of 1.69 (95% C.I.=1.45 to 1.98). Intensive counseling was found to be more effective than minimal advice, with a pooled odds ratio of 1.44 (95% C.I.=1.23 to 1.68).

A recent meta-analysis of five studies<sup>23</sup> found group counseling more effective than no intervention or minimal contact, with a pooled odds ratio of 1.91 (95% C.I.=1.20 to 3.04). In two trials that compared group counseling directly with individual counseling, there were no statistically significant differences between the two interventions.

The 1996 smoking cessation guidelines revealed an apparent dose-response curve between the *amount* of counseling and the smoking cessation rate. For contact less than or equal to three minutes, the adjusted odds ratio was 1.2 (95% C.I.=1.0 to 1.5), and for contact longer than 10 minutes, the adjusted odds ratio increased to 2.4 (95% C.I.=2.1 to 2.7). Counseling lasting

between three and 10 minutes had an intermediate adjusted odds ratio of 1.4 (95% C.I.=1.2 to 1.7). Results from the new PHS clinical practice guideline shows a similar trend.<sup>18</sup>

According to the 1996 guidelines, there is a similar relationship for the *duration* of individual counseling. Counseling with a duration of less than two weeks was found to be less effective than counseling that lasted more than eight weeks (adjusted odds ratio of 1.1 versus 2.7).

Counseling lasting between two and eight weeks showed intermediate effectiveness (adjusted odds ratio of 1.6). The *number* of counseling sessions also showed a similar dose-response relationship, with a trend toward increasing smoking cessation rates with increasing number of individual treatment sessions up to seven sessions. Preliminary results from the 2000 PHS clinical practice guideline shows an odds ratio of 1.4 (95% C.I.=1.1 to 1.7) for two to three sessions, an odds ratio of 1.9 (95% C.I.=1.6 to 2.2) for four to eight sessions, and an odds ratio of 2.3 (95% C.I.=2.1 to 3.0) for more than eight sessions.

In conclusion, all forms of counseling have statistically significant effects on smoking cessation, with individual counseling appearing to be the most effective method. Dose-response curves are available for length of time spent on each counseling session, number of sessions, and total duration of counseling intervention.

#### QUESTION 8. HOW EFFECTIVE IS PHARMACOTHERAPY?

In a recent meta-analysis of 91 trials,<sup>24</sup> nicotine replacement therapy (NRT) was more effective than the control in smoking cessation, with a pooled odds ratio of 1.72 (95% C.I.=1.60 to 1.84). Different forms of NRT produced moderately different results, shown in the table below. Since the confidence intervals around these estimates of effect overlapped, there was no evidence of a

significant difference in the effectiveness of the five types of NRT. The PHS clinical practice guideline shows a very similar trend in odds ratios.<sup>18</sup>

### **Effectiveness of Nicotine Replacement Therapy versus Control**

<b>Delivery Mechanism</b>	<b>Pooled Odds ratio</b>
Gum (49 studies)	1.63
Sublingual tablet (2 studies)	1.73
Patch (32 studies)	1.77
Inhaled nicotine (4 studies)	2.08
Nasal spray (4 studies)	2.27

A quantitative systematic review of four studies that compared bupropion-SR users with a control group<sup>25</sup> reported a pooled odds ratio of 2.73 (95% C.I.=1.90 to 3.94). Bupropion-SR is an antidepressant sold as Wellbutrin. Currently marketed toward smokers under the name Zyban, it is the only FDA-approved drug for smoking cessation other than NRT. The same review also reported that two studies of nortriptyline (a tricyclic antidepressant) had a pooled odds ratio of 2.83 (95% C.I.=1.59 to 1.03).

Three quantitative systematic reviews on clonidine<sup>17, 27</sup> (which included six studies, seven studies, and 10 studies, respectively) reported pooled odds ratios of 1.89 (95% C.I.=1.30 to 2.74) and 3.0 (95% C.I.=1.5 to 5.9), respectively, for the first two studies, and a quit rate of 5.7% (95% C.I. = -1.3% to 12.7%) in the third study for clonidine, compared with control. There was, however, a high incidence of dose-dependent side effects, particularly sedation and dry mouth. Clonidine is used to treat hypertension; it has not been approved by the FDA for smoking cessation.

Two quantitative systematic reviews<sup>17, 25</sup> found no effectiveness for anxiolytics such as buspirone, diazepam, or meprobamate.

#### QUESTION 9. HOW EFFECTIVE IS SELF-HELP?

Two systematic reviews have reported results on self-help interventions.<sup>17, 22</sup> In the first, a meta-analysis of 25 studies<sup>22</sup> reported a pooled odds ratio of 1.23 (95% C.I.=1.01 to 1.51) compared with control. In the second, a meta-analysis of twelve studies<sup>17</sup> reported a pooled odds ratio of 1.2 (95% C.I.=0.97 to 1.6) compared with control. (Similar results were reported in the 2000 Public Health Service clinical practice guideline.<sup>18</sup> These data indicate that self-help materials have a small practical effect on smoking cessation. Studies of helpline/hotline forms of self-help, used alone, had an odds ratio of 1.4 (95% C.I. = 1.1 to 1.8). There is no evidence that adding self-help materials to individual counseling or NRT improved smoking cessation rates.<sup>22</sup>

#### QUESTION 10. WHAT PRACTICE SETTINGS ARE EFFECTIVE?

##### *Interventions for patients hospitalized with smoking-related illness*

Hospitalization gives patients a unique opportunity to quit smoking, as all U.S. hospitals are smoke-free. We found nine studies of interventions with hospitalized patients. We considered conducting a meta-regression on hospital interventions versus usual care in hospitals, but this was not possible for several reasons. First, many studies did not use a pure control group. For example, some studies of NRT for hospitalized patients gave the placebo group counseling, self-help literature, etc. In many cases, the difference between NRT and placebo was insignificant if both groups were provided with counseling and follow-up. Second, the populations studied differed in their reasons for hospitalization. For example, some studies included only cardiac



patients, while others excluded cardiac patients. Most important, the interventions used were very heterogeneous.

The highest quit rates were found in two studies of cardiac patients.<sup>28, 29</sup> The high rates may have occurred because the immediacy of the situation was apparent to the patients; however, the reported rates may be biased upward, and there was no biochemical confirmation of smoking cessation. In studies where cotinine or carbon monoxide was used to verify self-reports (most other studies), cessation rates were far below those reported in the two studies that relied solely on self-reports. In general, interventions with follow-up calls or visits were shown to be more successful than those without, except in one study.<sup>30</sup>

#### *Free-standing smoking cessation programs*

There are very few inpatient or residential programs designed specifically for smoking cessation. In Minnesota, both Hazelden and the Mayo Clinic have such programs, but we found no controlled studies of them. Thus, we can not make a statement about the effectiveness of such programs. The only study we found of outpatient smoking cessation clinics was a randomized trial, but there was no pure control group.<sup>31</sup>

#### QUESTION 11. WHO IS MOST EFFECTIVE IN DELIVERING SMOKING CESSATION INTERVENTIONS?

We identified one systematic review that assessed nursing interventions specifically, and two meta-analyses that assessed the relative effectiveness of different providers. We also conducted our own meta-regression analysis focussing on the relative effectiveness of different providers.

In summary, the data support that many types of providers are effective. In two of three comparative meta-analyses, physician providers compared to non-physician providers had a

higher estimated odds ratio of effectiveness, and in one synthesis this difference was statistically significant.

#### QUESTION 12. DO CERTAIN INTERVENTIONS WORK BETTER FOR SPECIAL POPULATIONS?

We found only one controlled trial of smoking cessation interventions designed specifically for Latinos. Unfortunately, only two participants (one in the control group, one in the intervention) demonstrated cotinine-validated abstinence at both post-treatment and 12-month follow-up. More controlled trials of smoking cessation interventions for Latinos are necessary before we can make a statement on effectiveness.

We found five studies on African American population, only one of which showed statistically significant improvements in smoking cessation. We found no studies that demonstrate reduced or enhanced effectiveness of generic smoking cessation interventions among different ethnic/racial groups.

#### QUESTION 13 & 14. COSTS AND COST EFFECTIVENESS OF INTERVENTIONS

This section will discuss the cost and cost-effectiveness of different interventions studied in this review, including counseling, self-help, and mass media. It is important to note that medication costs are sometimes combined with these various interventions. The following table lists the average wholesale cost per dose and cost per day for these medications.<sup>33</sup>

## Costs of Smoking Cessation Medications

(average wholesale price)		
Medication	Cost per Dose	Cost per Day
Nicotine patch	\$3 each	\$3.00
Nicotine inhaler	\$1/10mg	\$1.50
OTC Nicotine gum	\$0.50/piece	\$5.00
Bupropion	\$1.40/150-mg pill	\$2.80
Clonidine*	\$0.25/0.2-mg pill	\$0.50

\* not FDA-approved for smoking cessation

The available evidence suggests that smoking cessation interventions are highly cost-effective when compared with other medical treatments and prevention programs.<sup>18, 34</sup> The widely held view of smoking cessation as the “gold standard” of healthcare cost-effectiveness is underscored by the fact that even the least cost-effective smoking intervention — the use of nicotine gum as an adjunct to physician counseling — is estimated to cost less than half the median cost per life-year saved of nearly 600 life-saving interventions.<sup>35</sup>

We reviewed 15 published studies examining the cost-effectiveness (C/E) of various smoking cessation programs and three review articles. Eight of the cost-effectiveness analyses (CEA) were medical practice-based and seven were community-based interventions. In general, community-based programs tended to be less cost-effective than practice-based interventions. Further, practice-based interventions generally applied more rigorous methodologies such as randomized clinical trials. All of the studies reviewed examined adult smokers, yet none solely targeted the elderly.

All of the studies reviewed saved life-years at a cost as low as several hundred dollars to a high of \$14,000, with a median value of about \$5,000 per life year saved. These findings are well below the estimates of most other health interventions. The principal shortcoming of this

literature is a lack of evidence on the effectiveness of smoking cessation programs for specific patient subgroups -- such as the elderly -- and their preferences for specific interventions. As Warner<sup>34</sup> noted, different interventions are effective for different people. A resource-intensive treatment may be cost effective for smokers who do not respond to less-intensive programs, but may not be successful for smokers attempting to quit for the first time. Further investigation is needed to determine the cost-effectiveness of various smoking cessation interventions on specific patient populations.

## **LIMITATIONS**

The primary limitation of the present systematic review—a limitation that is common to all such reviews—is the quantity and quality of the original studies. The studies we examined are extremely heterogeneous in terms of both the interventions tested and the specific populations or health care systems being studied. Furthermore, many of the study-level variables are highly idiosyncratic and intercorrelated (e.g., a study of patient education with nurses may also be a study of NRT in low-income African Americans). The correlation between intervention-level variables and population makes the assessment of the effects of the individual components challenging.

In addition, this study assumes that interventions will be as successful when targeted toward adults 65 years of age or older as when targeted toward younger populations. We had insufficient data to empirically test this assumption.

## CONCLUSIONS

1. Individual, telephone, and group counseling are all effective, with individual counseling being possibly most effective.
2. There is consistent evidence from multiple analyses that greater intensity of counseling yields higher smoking cessation rates.
3. Nicotine replacement therapy (NRT), clonidine, and bupropion are all effective as pharmacotherapy for smoking cessation, although clonidine is not approved by the FDA for this use.
4. Patients visiting physicians trained in smoking cessation had higher cessation rates than those visiting untrained physicians.
5. Health insurance benefits of 100% for both counseling and NRT produced the greatest number of quitters in a population.
6. There is good evidence that both medical and non-medical providers are effective at delivering smoking cessation services, but conflicting evidence about the relative degree of effectiveness between provider types.
7. Interventions with follow-up calls or visits are more effective than those without.
8. There are insufficient data to support or refute variations on smoking cessation interventions among special populations.

## RECOMMENDATIONS

Recommendations based on the evidence were formulated by a panel of experts on smoking cessation, health services research, medicine, and behavior change. The body of the report contains a list of these experts.

1. Smoking cessation interventions should be tested as a Medicare benefit.
2. Any demonstration project should include pharmacotherapy, physician visit, and/or telephone hotline. Group counseling should not be required, as most older smokers will avoid groups.
3. Primary care practitioners participating in smoking cessation demonstrations should be offered and encouraged to have training in this area.
4. There is no evidence that paying providers for outcomes will work, and there is considerable evidence that it will not. However, providers should be held accountable for their performance in accordance with the Public Health Service clinical practice guideline.<sup>18</sup> The five As (ask, advise, assess, assist, and arrange) should be documented in provider records.
5. As in any demonstration project, sufficient numbers of minorities and women should be included.

## INTRODUCTION

Smoking is the single most preventable cause of morbidity and mortality in the United States.

Smoking is a major risk factor for cardiovascular disease, chronic obstructive pulmonary disease, cancer, hypertension, diabetic complications and osteoporosis.<sup>1,2</sup> Tobacco use causes more than 430,000 deaths, and costs the United States between \$50 and \$73 billion in medical expenses each year.<sup>3,4</sup>

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Approximately 13% of people 65 and older reported that they were smokers in 1995.<sup>5</sup> Today's older smokers grew up in an era in which advertisers, even physicians, promoted smoking; the adverse effects of smoking had not yet been established. The consequences of smoking among this cohort are now evident. In 1990, smoking caused over 287,000 deaths in the U.S. among persons age 65 and older--about 70% of the U.S. smoking-related deaths that year.<sup>6</sup>

Zhang and colleagues estimated that smoking-related illnesses accounted for about \$14.2 billion in Medicare expenditures in 1993, about 9.4% of Medicare's total budget. More specifically, smoking accounted for 11.4% of hospital care, 11.3% of nursing home care, 5.9% of home health care, and 5.6% of ambulatory care.<sup>7</sup> It is estimated that between 1995 and 2015, tobacco-related diseases will cost Medicare about \$800 billion.<sup>8</sup>

There are significant benefits to smoking cessation, even after 30 or more years of regular smoking.<sup>9</sup> Data from the Established Population for the Epidemiological Study of Elderly (EPESE) indicate that smokers who quit have cardiovascular mortality rates similar to those of nonsmokers, and that this benefit is unrelated to age or the time elapsed since cessation.<sup>10</sup> In one study, older smokers who already had coronary artery disease improved their survival and risk of heart attack by quitting.<sup>11</sup> In addition, according to Tell,<sup>12</sup> lung function and circulation begin to improve immediately after cessation. A person who smokes more than 20 cigarettes per day and who quits at age 65 can expect to increase his or her life expectancy by 2 to 3 years.<sup>13</sup> Quitting smoking also greatly increases the quality of life for seniors.

Unfortunately, older smokers may be less likely to perceive the health consequences of smoking. For example, according to a recent survey of members of the American Association of Retired Persons (AARP), 47% of smokers age 50 and over did not believe that quitting could improve their health. In addition, 45% did not believe that continuing to smoke could further damage their health.<sup>14</sup> Still, older smokers are more likely to achieve success in their cessation attempts than younger smokers are.<sup>15, 16</sup> Thus, although special emphasis needs to be applied in addressing the barriers to quitting among the elderly, age is not a significant obstacle to cessation interventions.

A number of interventions to improve smoking cessation have been studied, and many of these are recommended in clinical practice guidelines promulgated by various organizations.<sup>17</sup> To better understand such interventions in the Medicare population, the Health Care Financing Administration (HCFA), as part of its Healthy Aging project, commissioned an evidence-based systematic review of smoking cessation, the results of which are detailed in this report.



## METHODS

We synthesize evidence from the scientific literature on effectiveness of smoking cessation programs, using the evidence review and synthesis methods of the Southern California Evidence Based Practice Center, an Agency for Healthcare Research and Quality designated center for the systematic review of literature on the evidence for benefits and harms of health care interventions. Our literature review process consisted of the following steps:

- Develop a conceptual model (also sometimes called an evidence model or a causal pathway).<sup>36</sup>
- Identify sources of evidence (in this case, sources of scientific literature).
- Identify potential evidence.
- Evaluate potential evidence for methodological quality and relevance.
- Extract study-level variables and results from studies meeting methodologic and clinical criteria.
- Synthesize the results.

The following are broad categories of interventions that can be used to promote smoking cessation among persons age 65 or older:

- self-help
- counseling
- pharmacotherapy
- education
- financial incentives – provider and patient
- regulatory and legislative interventions
- media campaigns.

These interventions are described below.

Self-help. In self-help interventions, a patient uses provided instructional materials to help himself/herself stop smoking.

Counseling. Counseling can be in person or via telephone, in individual or group therapy. Providers include peer counselors, social workers, psychologists, and psychiatrists. Medical doctors also often provide brief counseling.

Pharmacotherapy. Nicotine replacement therapy (NRT) can be administered by chewing gum, nasal spray, or transdermal patch. Clonidine, antidepressants, anxiolytics, and mecamylamine have also been prescribed in efforts to curtail patients' smoking.

Education. Patients may be educated in person or through the mail, by pamphlets, peer educators, newsletters, audiovisual materials, computers, or electronic publications. Providers can be educated about smoking cessation interventions by attending workshops, training sessions, or lectures.

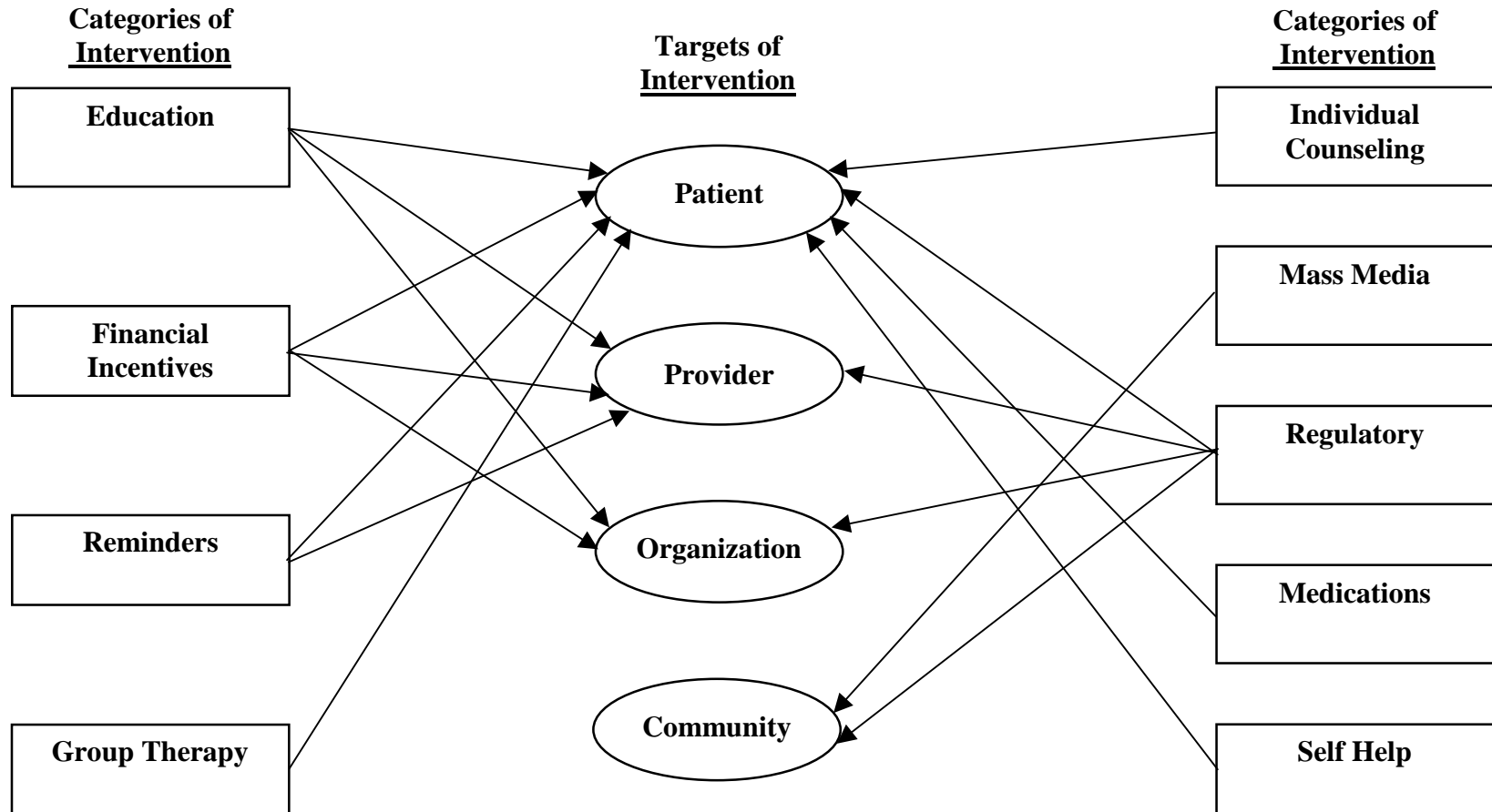
Financial incentives. Direct or indirect financial reward or benefit can be tied to a specific action on the part of a patient or provider. For example, patient insurance payments may be reduced, or gifts can be offered as a reward for biochemical confirmation of abstinence from tobacco.

Regulatory and legislative initiatives. Regulatory and legislative initiatives may operate on the local, state, or national level by creating new incentives or barriers that shape behavior. The most common policy changes include smoke-free workplaces and increased taxes on tobacco products.

Media campaigns. Media campaigns reach great numbers of people, through television, radio, newspapers, and billboards.

The relationships of these broad categories of interventions to the potential targets of smoking cessation interventions (patient, provider, organization, and community) are shown in Figure 1.

**Figure 1. Conceptual Model**



## **IDENTIFICATION OF LITERATURE SOURCES**

We used the sources described below to identify existing research and potentially relevant evidence for this report.

### COCHRANE COLLABORATION

The Cochrane Collaboration is an international organization that helps people make well-informed decisions about health care by preparing, maintaining, and promoting the accessibility of systematic reviews on the effects of health care interventions. The Cochrane Library contains both a database of systematic reviews and a controlled-trials register. The library receives additional material continuously to ensure that reviews are maintained through identification and incorporation of new evidence. The Cochrane Library is available on CD-ROM, by subscription.

The Cochrane Tobacco Group maintains a database (held in Reference Manager) of over 2,000 citations on tobacco cessation. About 1,300 report on controlled trials or other types of evaluations of interventions. Other references are held for their potential as background material. The search terms used by the Cochrane Tobacco Group are reproduced in Table 1. (Cochrane Library, 1999).

**Table 1. Literature Search Terms Used by the Cochrane Tobacco Group**

Medline

SMOKING CESSATION  
 "SMOKING-CESSATION"/ all subheadings  
 "TOBACCO-USE-DISORDER"/ all subheadings  
 "TOBACCO"/ all subheadings  
 "NICOTINE"/ all subheadings  
 "TOBACCO,-SMOKELESS"/ all subheadings  
 "SMOKING"/ prevention-and-control , therapy  
 (QUIT\* or STOP\* or CEAS\* or GIV\*) near SMOKING  
 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8  
 "SMOKING"/ all subheadings  
 #10 not #9  
 PT=RANDOMIZED-CONTROLLED-TRIAL  
 PT=CONTROLLED-CLINICAL-TRIAL  
 RANDOMIZED-CONTROLLED-TRIALS  
 RANDOM-ALLOCATION  
 DOUBLE-BLIND-METHOD  
 SINGLE-BLIND-METHOD  
 #12 or #13 or #14 or #15 or #16 or #17  
 PT=CLINICAL-TRIAL  
 explode CLINICAL-TRIALS / ALL  
 (CLIN\* near TRIAL\*) in TI  
 (CLIN\* near TRIAL\*) in AB  
 PLACEBOS  
 PLACEBO\* in TI  
 PLACEBO\* in AB  
 RANDOM\* in TI  
 RANDOM\* in AB  
 RESEARCH-DESIGN  
 (SINGL\* or DOUBL\* or TREBL\* or TRIPL\*) near (BLIND\* or MASK\*)  
 (#29 in TI) or (#29 in AB)  
 (VOLUNTEER\* or PROSPECTIV\*) in TI  
 (VOLUNTEER\* or PROSPECTIV\*) in AB  
 #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #30 or #32  
 explode "EVALUATION-STUDIES"/ all subheadings  
 explode "CROSS-SECTIONAL-STUDIES"/ all subheadings  
 "PROSPECTIVE-STUDIES"  
 "RETROSPECTIVE-STUDIES"  
 "FOLLOW-UP-STUDIES"  
 #34 or #35 or #36 or #37 or #38  
 explode "HEALTH-EDUCATION"/ all subheadings  
 explode "HEALTH-BEHAVIOR"/ all subheadings  
 explode "COMMUNITY-HEALTH-SERVICES"/ all subheadings  
 "HEALTH-PROMOTION"/ all subheadings

**Table 1 (continued)**

explode "BEHAVIOR-THERAPY"/ all subheadings

#40 or #41 or #42 or #43 or #44

#18 or #33 or #39 or #45

(TG=ANIMAL) not ((TG=HUMAN) and (TG=ANIMAL))

#46 not #47

#48 and #9 (First part of search - uses core smoking related terms, for maximum specificity)

#48 and #11 (Second part of search - highly sensitive, low specificity)

An updated search of PsycLIT (Psychological Abstracts - American Psychological Association) was developed and run retrospectively.

Updated PsycLIT search on Silverplatter ASCII3:

#1 SMOKING CESSATION

#2 ANTISMOKING or ANTI-SMOKING

#3 QUIT\* or CESSAT\*

#4 ABSTIN\* or ABSTAIN\*

#5 CONTROL\* NEAR SMOK\*

#6 explode "BEHAVIOR-MODIFICATION"

#7 #2 or #3 or #4 or #5 or #6

#8 PREVENT\*

#9 "TOBACCO-SMOKING" OR SMOK\* OR CIGAR\* OR TOBACCO\*

#10 #7 and #9

#11 #8 and #9

#12 #1 or #10 or #11

Dissertation Abstracts Online:

1 SMOKING ADJ CESSATION

2 SMOKING OR CIGARETTE\$1 OR TOBACCO

3 RANDOMIS\$ OR RANDOMIZ\$ OR (RANDOM ADJ ALLOCATS) OR (DOUBLE ADJ BLIND\$1)

4 PROSPECTIVE ADJ (STUDY OR STUDIES)

5 TRIAL\$1

6 2 AND (3 4 5)

7 1 OR 6

Applied Social Sciences Index & Abstracts (ASSX)

8 SMOKING ADJ CESSATION

9 SMOKING

10 RANDOMIS\$ OR RANDOMIZ\$ OR TRIAL\$1 OR (RANDOM ADJ ALLOCATS)

11 DOUBLE ADJ BLIND

12 PROSPECTIVE ADJ (STUDY OR STUDIES)

13 9 AND (10 11 12)

14 8 OR 13

Social Citations Index (SCI) and Social Science Citations Index (SSCI):

SMOK\* & (CESSAT\* OR TRIAL\* OR RANDOMI\* OR PROSPECTIVE OR BLIND)

### SMOKING CESSATION GUIDELINES

The Agency for Healthcare Research and Quality (AHRQ, formerly the Agency for Health Care Policy and Research, AHCPR) developed guidelines for smoking cessation in 1996. An advisory panel employed an explicit science-based methodology and expert clinical judgement to develop specific statements on smoking cessation interventions. Critical reviews and syntheses were used to evaluate empirical evidence and outcomes. More recently, the Public Health Service (PHS) has published a document, Treating Tobacco Use and Dependence, which evaluates literature from 1975 to 1999.<sup>18</sup> These findings were released in June 2000. We were provided with the list of references used in both analyses, and we ordered the documents not already in our possession. In preparing the Public Health Service clinical practice guideline, more than 50 meta-analyses were performed on type of counseling (phone, individual, group), length of counseling, intensity of program, etc. These analyses were not stratified by age.

### PREVIOUS SYSTEMATIC REVIEWS

We identified 10 previously completed systematic reviews relevant to this project from our personal files (see Table 2). Each review discusses one or more interventions aimed at smoking cessation. We retrieved all relevant documents referenced in these publications.



## Table 2. Previous Systematic Reviews

- Cepeda-Benito A. Meta-analytical review of the efficacy of nicotine chewing gum in smoking treatment programs. *J Consult Clin Psychol.* 1993;61:822-30.
- Covey LS, Glassman AH. A meta-analysis of double-blind placebo-controlled trials of clonidine for smoking cessation. *Br J Addict.* 1991;86:991-8.
- Curry SJ. Self-help interventions for smoking cessation. *J Consult Clin Psychol.* 1993;61:790-803.
- Fiore MC, Smith SS, Jorenby DE, Baker TB. The effectiveness of the nicotine patch for smoking cessation. A meta-analysis. *JAMA.* 1994;271:1940-7.
- Fisher EB Jr., Lichtenstein E, Haire-Joshu D, Morgan GD, Rehberg HR. Methods, successes, and failures of smoking cessation programs. *Annu Rev Med.* 1993;44:481-513.
- Kottke TE, Battista RN, DeFries GH, Brekke ML. Attributes of successful smoking cessation interventions in medical practice. A meta-analysis of 39 controlled trials. *JAMA.* 1988;259:2883-9.
- Pederson LL. Compliance with physician advice to quit smoking: A review of the literature. *Prev Med.* 1982;11:71-84.
- Silagy C, Mant D, Fowler G, Lodge M. Meta-analysis on efficacy of nicotine replacement therapies in smoking cessation. *Lancet.* 1994;343:139-42.
- Skaar KL, Tsoh JY, McClure JB, et al. Smoking cessation. 1: An overview of research. *Behav Med.* 1997;23:5-13.
- Ward KD, Klesges RC, Halpern MT. Predictors of smoking cessation and state of the art smoking interventions. *The Journal of Social Issues.* 1997;53:129-45.

## HEALTH CARE QUALITY IMPROVEMENT PROJECTS (HCQIP)

Each U.S. state and territory is associated with a Medicare Peer Review Organization (PRO) that conducts various research projects. HCFA maintains a database with a narrative description of each research project, called a Narrative Project Document (NPD). An NPD includes the aims, background, quality indicators, collaborators, sampling methods, interventions, measurement, and results of a project. We searched the NPD database for studies on smoking cessation. This

search retrieved only two NPDs, reflecting the lack of smoking intervention trials in the Medicare population.

#### SUPPLEMENTAL LIBRARY SEARCH

The Cochrane Library database contains records of studies published up to June 1997. We conducted a search of literature published since that date, using the terms used by the Cochrane Tobacco Group (Table 1), and we acquired copies of all relevant articles not already obtained through the sources mentioned above.

### **EVALUATION OF POTENTIAL EVIDENCE**

We reviewed the articles retrieved from the literature sources against exclusion criteria to determine whether to include them in the evidence synthesis. We created a one-page screening review form that contains a series of yes/no questions (Figure 2). After evaluation against this checklist, each article was either accepted for further review or rejected. A physician and a psychologist, each trained in the critical analysis of scientific literature, independently reviewed each study, abstracted data, and resolved disagreements by consensus. Dr. Erin Stone (the co-principal investigator of this study) resolved any disagreements that remained unresolved after discussions between the reviewers. Project staff entered data from the checklists into an electronic database that was used to track all studies through the screening process.

While we were searching primarily for data relevant to the Medicare population, we included studies containing data on populations under age 65 to avoid loss of potentially useful data. (We did exclude studies on adolescents and pregnant women, for obvious reasons.) The studies had to measure quit rates at least five months after the start of the intervention. To be accepted at this stage, a study had to use one of the following study designs: randomized controlled trial,

controlled clinical trial, controlled before and after study, or interrupted time series with adequate data points. We defined the study types according to the criteria described below.

*Randomized controlled trial (RCT).* A trial in which the participants (or other units) are definitely assigned prospectively to one or two (or more) alternative forms of health care, using a process of random allocation (e.g., random number generation, coin flips).

*Controlled clinical trial (CCT).* A trial in which participants (or other units) are either:

- a) Definitely assigned prospectively to one or two (or more) alternative forms of health care using a quasi-random allocation method (e.g., alternation, date of birth, patient identifier),

OR

- b) Possibly assigned prospectively to one or two (or more) alternative forms of health care using a process of random or quasi-random allocation.

*Controlled before and after study (CBA).* A study in which the intervention and control groups become involved in the study in a way other than by random process and in which the baseline period of assessment is included in the main outcomes. We used two minimum criteria for inclusion of CBAs in the review:

- a) Contemporaneous data collection – data on the pre- and post-intervention periods for the study and control sites are the same,
- b) Appropriate choice of control sites – the study and control sites are comparable with respect to dominant reimbursement system, level of care, setting of care, and academic status.

*Interrupted time series (ITS).* An ITS study examines data trends and attributes a change in trend to an intervention. Such studies can be either retrospective or prospective. We used two minimum criteria for inclusion of ITS designs in the reviews:

- a) A clearly defined point in time at which the intervention occurred.

- b) At least three data points before and three data points after the intervention.

Following these restrictions on study design, we excluded studies that employed a simple pre/post design (i.e., a study design in which an intervention is administered to providers, patients, or communities, and the proportion of persons receiving the service is recorded once before and once after the intervention). Such a study design has no control group; therefore, it cannot account for temporal effects unrelated to the intervention.

**Figure 2. Screening Form**  
**Topic = SMOKING CESSATION**  
**HCFA - Healthy Aging Evidence Report #2**

### Reject Code

1. Article ID Topic :  
2. First Author \_\_\_\_\_  
(First 8 character of first author's last name)

3. Reviewer \_\_\_\_\_

4. Subject of article:
- |                         |   |
|-------------------------|---|
| Smoking cessation ..... | 1 |
| Other .....             | 9 |

**(IF OTHER, REJECT - STOP)**

5. Study Design:
- |             |   |
|-------------|---|
| RCT .....   | 1 |
| CCT .....   | 2 |
| CBA .....   | 3 |
| ITS .....   | 4 |
| Other ..... | 9 |

**(IF OTHER, REJECT - STOP)**

6. Age:
- |                                 |   |
|---------------------------------|---|
| 65 years and over only.....     | 1 |
| Under 65 and over 65 .....      | 2 |
| Adults under 65 only .....      | 3 |
| Not adult (e.g. teenager) ..... | 4 |
| Other (specify:.....)           | 9 |

**(IF OTHER OR NOT ADULT, REJECT - STOP)**

7. If under 65 and over 65:  
Are the results split out by these age groups?
- Yes..... 1  
No ..... 2

8. Country of subjects:
- |             |   |
|-------------|---|
| USA .....   | 1 |
| Other ..... | 9 |
9. Was smoking cessation assessed by:
- |   |   |
|---|---|
| Patient report.....   | 1 |
| Biochemical confirmation<br>(e.g. thiocyanate,<br>cotinine, nicotine,<br>carboxyhemoglobin<br>levels) ..... | 2 |
| 3 <sup>rd</sup> party .....   | 3 |
| Other (specify:.....)   | 9 |

10. Number of months after treatment that LAST follow-up occurred:
- |                           |    |
|---------------------------|----|
| Less than one month ..... | 0  |
| One.....                  | 1  |
| Two .....                 | 2  |
| Three.....                | 3  |
| Four.....                 | 4  |
| Five .....                | 5  |
| Six .....                 | 6  |
| Seven.....                | 7  |
| Eight.....                | 8  |
| Nine.....                 | 9  |
| Ten .....                 | 10 |
| Eleven .....              | 11 |
| Twelve .....              | 12 |
| More than 12 (specify:    |    |
| _____ months)             |    |

--

## **EXTRACTION OF STUDY-LEVEL VARIABLES AND RESULTS**

We abstracted data from the relevant articles on a specialized form (see Figure 3). The form contains questions about the study design; the number and characteristics of the patients; the setting, location, and target of the intervention; the intensity of the intervention; the types of outcome measures; the time from intervention until outcome measurement; and the results. We selected the variables for abstraction with input from the project's technical experts. A physician and a psychologist, working independently, extracted data in duplicate and resolved disagreements by consensus. A senior physician resolved any disagreements not resolved by consensus.

To evaluate the quality of the study, we collected information on the study design (with the hierarchy of internal validity being RCT, CCT, CBA, and ITS), withdrawal/dropout rate, and agreement between the unit of randomization and the unit of analysis. We did not use blinding and concealment of allocation,<sup>37</sup> because those techniques were not feasible in many studies of smoking cessation interventions. The primary outcome consisted of the proportion of clients who quit smoking in the control and intervention groups. Many studies confirmed quit rates biochemically by measuring breath carbon monoxide, saliva cotinine, or serum thiocyanate. If confirmed numbers were unavailable, we extracted self-report data.

**Figure 3. Abstraction Form**  
**Smoking - HCFA-Healthy Aging - Evidence Report #2**

1.	Article ID: _____	ID 1-5
2.	Study number within ID: _____	SUBID 6-7
	Describe: _____	CARD 01
3.	First Author: _____	10-17
4.	Reviewer: _____	
5.	Date of publication: 1 9 ____	18-19

6. Are any vulnerable populations specifically included?

	Yes	No	
Persons 85 and older .....	1	2	20
African-Americans .....	1	2	21
Hispanic .....	1	2	22
Other minority populations .....	1	2	23
Low-income populations .....	1	2	24
Nursing home .....	1	2	25
Pregnant women .....	1	2	26
Other (specify: _____) .....	1	2	27

7. Target of the intervention:

	Yes	No	
Patients .....	1	2	28
Providers .....	1	2	29
Organizations .....	1	2	30
Community			
other geographic area .....	1	2	31

8. If PROVIDER is targeted, what best characterizes the provider type?

	Yes	No	
Physicians .....	1	2	32
Nurses .....	1	2	33
Dentist .....	1	2	34
Pharmacist .....	1	2	35
Psychologist .....	1	2	36
Counselor .....	1	2	37
Social Worker .....	1	2	38
Other (specify: _____) .....	1	2	39
Provider is not target .....	1		40

9. What is the setting of the intervention? 41

Academic setting .....	1	
Non-academic setting .....	2	
Both academic and		
Non-academic setting .....	3	
Not sure .....	4	

10. What is the geographic setting of the intervention? 42

Mainly rural .....	1	
Mainly urban/suburban .....	2	
Mixed rural/urban/suburban .....	3	
Not sure .....	4	

11. In what health-care practice settings did the intervention occur? 43

Hospital .....	1	
Outpatient, clinic/program .....	2	
Outpatient, w/primary-care physician .....	3	
Outpatient, not P-C physician .....	4	
Outpatient, other (specify _____) .....	5	
Both hospital and outpatient .....	6	
Nursing home .....	7	
Not applicable .....	9	

12. What best describes the reimbursement system of the care in which the intervention occurred? 44

Fee-for-service .....	1	
HMO .....	2	
Managed care, not HMO .....	3	
Mixed reimbursement		
systems .....	4	
Other (specify: _____) .....	5	
Not applicable .....	9	

13. Comorbid conditions/other cessation-affecting factors:

	Included	Excluded	Neither	
High nicotine dependence .....	1	2	3	45
Proximity to other smokers .....	1	2	3	46
High stress level .....	1	2	3	47
Concern about weight gain .....	1	2	3	48
Psychiatric comorbidity .....	1	2	3	49
Other (specify: _____) .....	1	2	3	50

**Figure 3: Abstraction Form (continued)**  
**Smoking - HCFA-Healthy Aging Evidence Report #2**

14. What was the unit of allocation?	51	17. Was there a sample-size justification or power calculation?	54
Patient .....	1	Yes .....	1
Provider.....	2	No .....	2
Organization.....	3		
Community or		18. What outcomes were measured?	55
geographic area .....	4	Proportions/percents .....	1
Not applicable .....	9	Other .....	2 (If Other, give to Erin)
15. What was the unit of analysis?	52	19. When were the outcomes last measured relative to after the start	
Patient .....	1	of the intervention?	56-58
Provider.....	2		
Organization.....	3	_____ weeks	
Community or			
geographic area .....	4	20. Were costs analyzed?	59
Not applicable .....	9	Yes .....	1 (If Yes, give to Erin)
		No .....	2
16. If the unit of allocation and the unit of analysis are not the same,		21. Is this a crossover study?	60
was any statistical correction made for clustering?	53	Yes .....	1
Yes .....	1	No .....	2
No .....	2		
Not applicable .....	9		



**Figure 3: Abstraction Form (continued)**  
**Smoking - HCFA-Healthy Aging Evidence Report #2**

**GROUP 1 / 2 / 3 / 4 / 5** (Complete this page for each intervention arm)

Description of group (optional): \_\_\_\_\_

23. What best characterizes the intervention for this group?

Description of Intervention	X	Intensity	Duration	# Times	Medium	Content
01 Control/Usual Care/No intervention						
02 Education without detailing/outreach						
A Patient						
B Provider						
03 Detailing						
04 Provider feedback						
05 Financial/administrative intervention						
A Patient						
B Provider						
C Organization						
06 Reminders						
A Patient						
B Provider						
07 Group therapy/counseling						
A Leader trained						
B Leader not trained						
08 Individual counseling						
09 Mass media/community intervention						
10 Regulatory						
A Patient						
B Provider						
C Organization						
11 Medications		Dose (mg)	Duration days	Times/Day		
A Nicotine Replacement						
1 Gum						
2 Patch						
3 Nasal spray						
B Clonidine						
C Antidepressants						
D Anxiolytics						
E Mecamylamine						
F Other drug (                      )						
12 Self-help						
13 Organizational (process) change						

ID 1-5  
SUBID 6-7  
CARD 02

24. Does the intervention include any of the following?

	Yes	No	
Social influence.....	1.....2		10
Marketing/Outreach .....	1.....2		11
High visual appeal/clarity .....	1.....2		12
Collaboration, teamwork.....	1.....2		13
Design based on needs, barriers, incentives, assessments, or theory.....	1.....2		14
Top management support.....	1.....2		15
Active learning strategies.....	1.....2		16

25. How many patients were...

Enrolled        \_\_\_\_\_ , \_\_\_\_\_        17-22

Followed        \_\_\_\_\_ , \_\_\_\_\_        23-28

**Figure 3: Abstraction Form (continued)**  
**Smoking - HCFA-Healthy Aging Evidence Report #2**

**Describe the outcomes:**

**SMOKING CESSATION**

Group	Percent not smoking before intervention	Percent not smoking after intervention	Sign (< = >)	p-value	Comparison group	
<b>1</b>	____ _ . ____	____ _ . ____	____	____ . ____ _	____	ID 1-5 SUBID 6-7 CARD 07  10-24
			____	____ . ____ _	____	25-31
<b>2</b>	____ _ . ____	____ _ . ____	____	____ . ____ _	____	32-46
			____	____ . ____ _	____	47-53
<b>3</b>	____ _ . ____	____ _ . ____	____	____ . ____ _	____	54-68
			____	____ . ____ _	____	69-75
<b>4</b>	____ _ . ____	____ _ . ____	____	____ . ____ _	____	76-90
			____	____ . ____ _	____	91-97
<b>5</b>	____ _ . ____	____ _ . ____	____	____ . ____ _	____	98-112
			____	____ . ____ _	____	113-119

**Figure 3: Abstraction Form (continued)**  
**Smoking - HCFA-Healthy Aging Evidence Report #2**

**ADDITIONAL INSTRUCTIONS**

**Intensity:** Length of time in minutes for each unit of intervention, e.g. 60 minute educational session, 1 minute TV spot, 5 minute counseling session.

**Duration:** Length of time in days from start of intervention to end of intervention. E.g. TV spots ran for 15 days, educational session occurred only once (1 day), nicotine replacement therapy given for 4 weeks (28 days).

**Number of units of intervention:** Number of times the intervention occurred for each target. E.g. 1 counseling session each week for 5 weeks for each patient (5 units), 2 reminders sent to each patient (2 units), 1 brochure given to each patient (1 unit).

**Medium/Delivery vehicle of intervention.** Write down number(s) from list below (3 numbers max):

1. In person
2. By telephone
3. In group
4. Radio
5. Broadcast TV
6. Billboard
7. Electronic
8. Video
9. Internet (web site)
10. Poster
11. Mail
12. Other
13. Printed material (e.g. newsprint, brochure, computer printout)
14. Other Visual Display

**Content:** Was there mention that the content was tailored to the audience (e.g. ethnically sensitive billboard)? Write **Y** for Yes and **N** for No.

## **EXPERT PANEL REVIEW OF EVIDENCE REPORT**

We presented the draft evidence report to a panel of experts (Table 3) for feedback and discussion on October 21, 1999. During this meeting, we reviewed our methods and preliminary results. We also presented draft models for smoking cessation demonstration projects in fee-for-service and managed-care settings. Feedback from the expert panel was useful in fine-tuning both our analysis and our proposed intervention demonstration projects.

**Table 3. Expert Panel**

**Susan Curry, Ph.D.**

Associate Director  
Center for Health Studies  
Group Health Cooperative of Puget Sound

**Michael Fiore, M.D., M.P.H.**

Professor of Medicine  
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**Disclaimer: Participation as an Expert Panelist does not indicate consensus with the recommendations of this evidence report**

## STATISTICAL METHODS

Prior to our analysis, we entered all data on outcomes and interventions into the statistical program SAS.<sup>38</sup> In the analysis itself, we sought to answer a variety of questions specified by HCFA:

1. If Medicare were to offer a smoking cessation benefit, how would providers be reimbursed? For example, by minutes of counseling?
2. How useful is provider training?
3. How should provider compliance be measured and monitored?
4. What means could be used to curb overutilization? Cost sharing by patients? Annual caps on services?
5. How effective are patient financial incentives?
6. How effective is telephone counseling?
7. How effective is other counseling?
8. How effective is pharmacotherapy?
9. How effective is self-help?
10. Which practice settings are most effective? Outpatient? Hospital? Free-standing smoking cessation clinics?
11. Who is most effective at delivering smoking cessation interventions? Physicians? Psychologists? Nurses? Dentists?
12. Do certain interventions work better for special populations?
13. What are costs of interventions?
14. Which interventions are most cost-effective?

Some of these questions were similar or even identical to questions being assessed by the team leading the 2000 Public Health Service (PHS) clinical practice guideline on smoking cessation guidelines. However, the focus of this report was to draw inferences for Medicare programs and policies for an insurance benefit. Here we present the PHS analyses where applicable.<sup>18</sup>

Our summary of the evidence is both qualitative and quantitative. For many of the specific questions listed above, the evidence was too sparse and/or heterogeneous to support statistical pooling. In these cases, our summary of evidence is qualitative. For those questions that had sufficient information to support statistical pooling, we used meta-regression.

#### META-REGRESSION ANALYSIS

We first retrieved all studies that assessed the effects of an intervention or interventions relative to either a group that received usual care or a control group. We then fit a series of meta-regressions to these studies.<sup>39</sup> The basic data matrix for the meta-regressions was as follows. Each study with a single intervention arm contributed four observations corresponding to the cells of a two-by-two table of treatment by outcome (control and intervention cases that received the preventive or screening service; control and intervention cases that did not) to a weighted logistic regression that predicted cessation of smoking or no cessation. An observation's weight was equal to the number of individuals belonging to the corresponding cell. Studies that had more than one intervention contributed an additional pair of observations (those who did not and those who did receive the service in the intervention group, respectively) for each additional intervention. For example, a study that had three intervention arms contributed eight observations to the meta-regression: two for the control group, two for the first intervention, two for the second intervention, and two for the third intervention.

To assess the statistical significance of each type of intervention, or of the interaction between treatment and a particular covariate of interest—for example, whether intervening worked better for particular subpopulations—we constructed specific models that contained both an intervention component indicator or specific covariate-by-treatment interaction indicator and

indicator variables for each study. The inclusion of study indicators controlled for all measured study characteristics and all unmeasured ones and is akin to fitting a fixed-effects model. Each model produced odds ratios versus control or usual care for covariate-by-treatment interactions that are adjusted for all measured and unmeasured study-level differences.

#### COST EFFECTIVENESS

To assess the cost-effectiveness of the interventions, we first determined whether the studies included cost data. We chose to summarize these studies qualitatively because of heterogeneity.

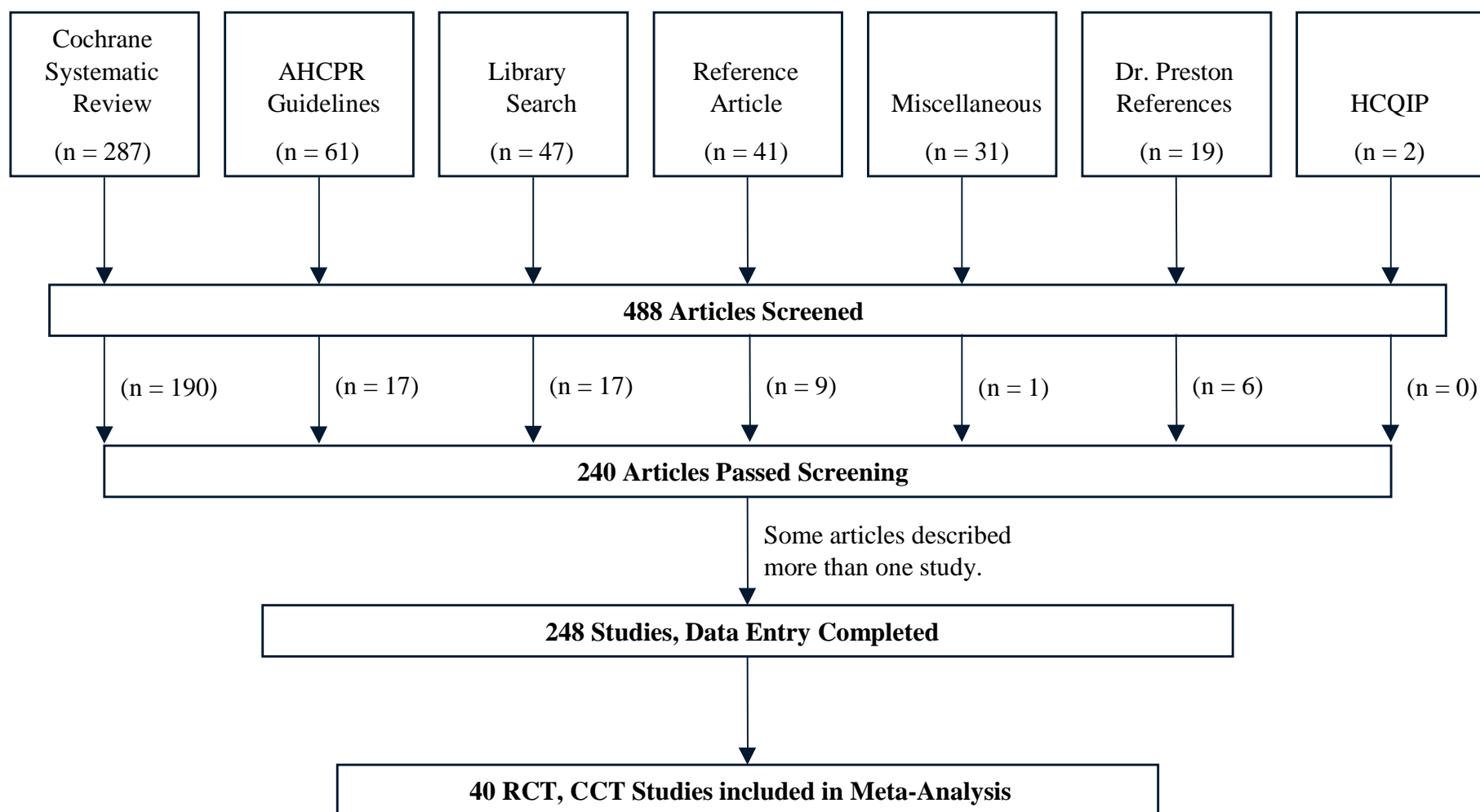


## **RESULTS**

### **IDENTIFICATION OF EVIDENCE**

Figure 4 describes the flow of evidence from the original sources to final acceptance for our review. The Cochrane library contained 287 relevant articles, the Public Health Service clinical practice guideline<sup>18</sup> referenced 61 articles not contained in Cochrane, and 41 additional articles were referenced in previous reviews on smoking cessation. Dr. Jeanette Preston, Principal Investigator of our smoking cessation demonstration project, sent 19 additional articles. A final library search yielded 47 recently published articles that were not contained in the former sources. The database for the Health Care Quality Improvement Projects contained only two reports on smoking cessation. Finally, 31 miscellaneous articles were identified from nonreview article reference lists and through suggestions from experts in the field.

**Figure 4. Flow of Evidence**



## **DISTRIBUTION OF EVIDENCE**

Table 4 presents the 248 studies we examined, stratified by service and broad characterization of intervention. Note that some studies addressed several interventions; therefore, the total sums to more than 248.

The intervention type that appeared in the greatest number of studies was patient education (149 studies), followed by individual counseling (118 studies). One-hundred four studies included self-help interventions, while 76 studies considered patient financial incentives. Once again, these categories were not mutually exclusive. For example, a patient could receive both education and group counseling simultaneously in a study. The number of interventions/arms ranged from one to nine; the average number of interventions was between two and three.

**Table 4. Interventions by Type**

<b>Intervention</b>	<b># of studies*</b>
Education without detailing/ outreach	
Patient	149
Provider	31
Provider detailing	3
Provider feedback	1
Financial/administrative intervention	
Patient	76
Provider	2
Organization	1
Reminders	
Patient	33
Provider	15
Group therapy/ counseling	
Leader trained	52
Leader not trained	32
Individual counseling	118
Mass media, community intervention	6
Regulatory	
Patient	0
Provider	0
Organization	1
Medications	
Nicotine replacement	
Gum	74
Patch	36
Nasal Spray	9
Clonidine	6
Antidepressants	6
Anxiolytics	5
Mecamylamine	3
Other	21
Self-help	104
Organizational (process) change	8

\* The numbers of studies in this column do not sum to the total number of articles because many studies use multiple interventions.

## DESCRIPTION OF EVIDENCE

The tables in Appendix 1 present the following descriptive information for each study that met our acceptance criteria:

- The author, year, country of origin, and study design.
- The age and vulnerable population targeted in the study.
- The target of the intervention (patients, provider type, organizations, communities).
- The study's setting (academic or nonacademic), the geographic setting (urban/suburban or rural), and the setting's reimbursement system (HMO, fee-for-service, mixed).
- The interventions being compared (e.g., control versus patient education, provider reminder versus provider reminder plus patient education).
- The characteristics of the interventions (population size [N], baseline rate, and follow-up rate).
- The smoking cessation rate in the control and intervention groups.

## QUALITY OF EVIDENCE

Of the 248 separate studies included in our analysis, 202 were randomized clinical trials (RCT), 32 were controlled clinical trials, 13 were controlled before/after studies, and 1 was an interrupted time series. Thus, the majority of studies used RCT, the study design with the strongest internal validity. Studies measured smoking cessation by patient self-report, by biochemical validation, or by both. We assessed with meta-regression whether use of self-report or biomedical validation was associated with bias in the estimated efficacy of interventions, controlling for other study-level variables. The adjusted odds ratio for all studies using biochemical validation was 2.62 (95% C.I.=2.38 to 2.87), while for self-report, the adjusted odds ratio was 2.48 (95% C.I.=2.21 to 2.78). Therefore, there is no evidence of bias in the estimate of efficacy as a function of method for measuring smoking cessation.

## DESCRIPTION OF RESULTS

### QUESTION 1. HOW SHOULD PROVIDERS BE REIMBURSED?

We found no direct evidence that any particular reimbursement system for providers is better than the others. (That is, there were no studies that compared smoking cessation outcomes as a function of different reimbursement schemes.) There did, however, appear to be a relationship between length of counseling time and smoking cessation outcomes. This is detailed in Question 6 below.

### QUESTION 2. HOW USEFUL IS PROVIDER TRAINING?

A recent meta-analysis<sup>19</sup> found 11 studies of the effect of provider education on both provider performance and patient smoking cessation rates. Some of these studies, published from 1988 through 1996, were required to report smoking cessation rates of at least six months after the intervention period. Two articles reported updates on previously published articles, leaving nine separate studies to be analyzed. Eight of these studies reported the effect of training medical practitioners, and one reported the effect of training dental practitioners. All of the studies were conducted in North America. The provider training in all studies was conducted on a group basis, in either a tutorial or a workshop format. Various methods were employed, including videos, role-playing, discussion, and didactic lectures. The content for most of these educational interventions included setting quit dates and offering patient follow-up.

The results of this review showed that trained providers are significantly more likely to perform smoking-cessation tasks than untrained providers. Patient outcomes are also affected. Patients who saw trained providers were more likely to stop smoking than those who saw untrained providers (pooled odds ratio 1.48, 95% C.I.=1.20 to 1.83).

### QUESTION 3. HOW SHOULD PROVIDER COMPLIANCE BE MEASURED AND MONITORED?

We found no studies in the medical literature that addressed the measuring and monitoring of provider compliance in smoking cessation interventions. Patient compliance was often measured by biochemical means such as serum cotinine, breath carbon monoxide, and thiocyanate.

### QUESTION 4 & 5. WHAT MEANS CAN BE USED TO CURB OVERUTILIZATION AND HOW EFFECTIVE ARE PATIENT FINANCIAL INCENTIVES?

One article studied effectiveness and cost-effectiveness of different levels of coverage for both a behavior modification benefit and a nicotine replacement benefit for smoking cessation. This study was performed at a health maintenance organization in the Pacific Northwest and involved over 90,000 patients.<sup>20</sup> The four benefit strategies are shown in Table 5.

**Table 5. Cost-sharing Plans Analyzed**

<b>Plan</b>	<b>Behavior Benefit</b>	<b>Nicotine Replacement Benefit</b>	<b>Cost/ Quitter</b>
Full	100%	100%	\$1171
Standard	50%	100%	\$797
Flipped	100%	50%	\$870
Reduced	50%	50%	\$801

The most cost-effective benefit plans (from the health plan perspective) were found to be those in which the patients bore some financial responsibility for the smoking cessation program. However, full coverage of both benefits resulted in more quitters (approximately two to four times as many quitters in the full benefit plan as in the reduced coverage plans).

We found no studies that specifically addressed curbing overutilization or the effect of capitation limits on services. Our expert panel emphasized that overutilization should not be a problem, and that we should concentrate on convincing smokers to engage in cessation interventions.

#### QUESTION 6 & 7. HOW EFFECTIVE IS TELEPHONE AND OTHER COUNSELING?

Individual counseling was statistically significantly superior to self-help (which was only marginally different than control). A number of systemic reviews have reported on various aspects of counseling for smoking cessation.<sup>17, 18, 21-23</sup> Results from a meta-analysis performed for the 2000 Public Health Service clinical practice guideline<sup>18</sup> show that all forms of counseling are statistically significantly effective at promoting smoking cessation. In the meta-analysis, individual counseling yielded the highest adjusted odds ratio for success, followed by group counseling, phone counseling, and self help. The greater effectiveness of individual counseling over telephone counseling approached statistical significance. There was no statistically significant difference in effectiveness between group counseling and telephone counseling. In another quantitative systematic review that examined only physician counseling,<sup>21</sup> 16 trials reporting the effect of brief advice on smoking cessation had a pooled odds ratio of 1.69 (95% C.I.=1.45 to 1.98). Intensive counseling was also found to be more effective than minimal advice, with a pooled odds ratio of 1.44 (95% C.I.=1.23 to 1.68).

A recent meta-analysis of five studies<sup>23</sup> found group counseling more effective than no intervention or minimal contact, with a pooled odds ratio of 1.91 (95% C.I.=1.20 to 3.04). In two trials that compared group counseling directly with individual counseling, there were no statistically significant differences between the two interventions.



The 1996 AHCPR systematic review<sup>17</sup> revealed an apparent dose-response curve between the amount of counseling and the smoking cessation rate. For contact less than or equal to three minutes, the adjusted odds ratio was 1.2 (95% C.I.=1.0 to 1.5), and for contact longer than 10 minutes, the adjusted odds ratio increased to 2.4 (95% C.I.=2.1 to 2.7). Counseling lasting between three and 10 minutes had an intermediate adjusted odds ratio of 1.4 (95% C.I.=1.2 to 1.7). Results from the Public Health Service clinical practice guideline show a similar trend.<sup>18</sup>

According to the guidelines, there is a similar relationship for the duration of individual counseling. Counseling with a duration of less than two weeks was found to be less effective than counseling that lasted more than eight weeks (adjusted odds ratio of 1.1 versus 2.7). Counseling lasting between two and eight weeks showed intermediate effectiveness (adjusted odds ratio of 1.6). The number of counseling sessions also showed a similar dose-response relationship, with a trend toward increasing smoking cessation rates with increasing number of individual treatment sessions up to seven sessions. The preliminary results from the update show an odds ratio of 1.4 (95% C.I.=1.1 to 1.7) for two to three sessions, an odds ratio of 1.9 (95% C.I.=1.6 to 2.2) for four to eight sessions, and an odds ratio of 2.3 (95% C.I.=2.1 to 3.0) for more than eight sessions.

In conclusion, all forms of counseling have statistically significant effects on smoking cessation, with individual counseling appearing to be the most effective method. Dose-response curves are available for length of time spent on each counseling session, number of sessions, and total duration of counseling intervention.

#### QUESTION 8. HOW EFFECTIVE IS PHARMACOTHERAPY?

In a recent meta-analysis of 91 trials,<sup>24</sup> NRT was found to be more effective than control in smoking cessation, with a pooled odds ratio of 1.72 (95% C.I.=1.60 to 1.84). Different forms of NRT showed moderately different results, as displayed in Table 6. Since the confidence intervals around these estimates of effect overlapped, there was no evidence of a significant difference in the effectiveness of the five types of NRT. The 2000 Public Health Service clinical practice guideline notes a very similar trend in odds ratios.<sup>18</sup>

**Table 6. Effectiveness of Nicotine Replacement Therapy versus Control**

<b>Delivery Mechanism</b>	<b>Pooled Odds ratio</b>
Gum (49 studies)	1.63
Sublingual tablet (2 studies)	1.73
Patch (32 studies)	1.77
Inhaled nicotine (4 studies)	2.08
Nasal spray (4 studies)	2.27

Bupropion, an antidepressant sold as Wellbutrin, is currently marketed toward smokers under the name Zyban and is currently the only FDA approved drug for smoking cessation other than NRT. A recent quantitative systematic review<sup>25</sup> reported a pooled odds ratio of 2.73 (95% C.I.=1.90 to 3.94) for four studies that compared results for bupropion users with those for a control group. The same review also reported that two studies of nortriptyline (a tricyclic antidepressant) had a pooled odds ratio of 2.83 (95% C.I.=1.59 to 1.03).

Three quantitative systematic reviews on clonidine<sup>17, 26, 27</sup> (which included six studies, seven studies, and 10 studies, respectively) reported pooled odds ratios of 1.89 (95% C.I.=1.30 to 2.74)

and 3.0 (95% C.I.=1.5 to 5.9), respectively, for the first two studies, and a quit rate of 5.7% (95% C.I. = -1.3% to 12.7%) in the third study for clonidine compared with control. There was, however, a high incidence of dose-dependent side effects, particularly sedation and dry mouth. Clonidine is used to treat hypertension and has not been approved by the FDA for smoking cessation.

Two quantitative systematic reviews<sup>17, 25</sup> found no effectiveness for anxiolytics such as buspirone, diazepam, or meprobamate.

#### QUESTION 9. HOW EFFECTIVE IS SELF-HELP?

Two systematic reviews have reported results on self-help interventions.<sup>17, 22</sup> In the first,<sup>22</sup> a meta-analysis of 25 studies reported a pooled odds ratio of 1.23 (95% C.I.=1.01 to 1.51) compared with control. In the second,<sup>17</sup> a meta-analysis of twelve studies, the pooled odds ratio was 1.2 (95% C.I. 0.97 to 1.6) compared with control. Similar preliminary results were noted in the Public Health Service clinical practice guideline.<sup>18</sup> These data indicate that self-help materials have a small practical effect on smoking cessation.

Studies of helpline/hotline forms of self-help, used alone, had an odds ratio of 1.4 (95% C.I.=1.1 to 1.8). There is no evidence that adding self-help materials to individual counseling or nicotine replacement therapy improved smoking cessation rates.<sup>22</sup>

#### QUESTION 10. WHAT PRACTICE SETTINGS ARE MORE EFFECTIVE?

##### *Interventions for patients hospitalized with smoking-related illness*

In their 1996 guidelines, the AHCPR recommended that all smokers be assisted with quitting during any hospitalization, using any treatment identified as effective by AHCPR. This was also

recommended by the new Public Health Service clinical practice guideline.<sup>18</sup> Hospitalization gives patients a unique opportunity to quit smoking, as all U.S. hospitals are smoke-free. In addition, the hospitalization may have been caused by a smoking-related illness, thus increasing awareness of the dangers of smoking. We considered conducting a meta-regression on hospital interventions versus usual care in hospitals, but this was not possible for several reasons. First, many studies did not use a pure control group. For example, some studies of NRT for hospitalized patients gave the placebo group counseling, self-help literature, etc. In many cases, the difference between NRT and placebo was insignificant if both groups were provided with counseling and follow-up. Second, the populations studied differed in their reasons for hospitalization. For example, some studies included only cardiac patients, while others excluded cardiac patients. Most important, the interventions used were very heterogeneous. Table 7 describes these interventions.

The highest quit rates were found in two studies of cardiac patients.<sup>28, 29</sup> The high rates may have occurred because the immediacy of the situation was apparent to the patients. However, the reported rates may be biased upward, and there was no biochemical confirmation of smoking cessation. In studies where cotinine or carbon monoxide was used to verify self-reports (most other studies), cessation rates were far below those reported in the two studies that relied solely on self-reports. In general, interventions with follow-up calls or visits were shown to be more successful than those without, except in the Rigotti study (1997).

**Table 7. Interventions with Hospitalized Patients**

First Author	Year	Population	N	Intervention	Quit Rate	Months	Verified
Burt	1974	Male heart attack survivors	125	Dogmatic advice to quit, pamphlet, follow-up by community nurse	62.0%	12	No
			85	Conventional advice to quit	27.5%	12	No
Campbell	1991	Patients with smoking-related respiratory or cardiovascular disease	106	Advice to quit, follow-up by counselor at 2,3,5,13, and 26 weeks, placebo gum	20.0%	12	Yes
			106	Advice to quit, follow-up by counselor at 2,3,5,13 and 26 weeks, nicotine gum	20.0%	12	Yes
Stevens	1993	All smokers hospitalized over 36 hours, expect post-partum or substance abusers	453	20 minute counseling session, 12 minute video, self-help materials, one or two follow-up calls	13.5%	12	No
			666	Usual care	9.2%	12	No
Campbell	1996	Patients with smoking-related respiratory or cardiovascular disease	119	Advice to quit, follow-up by counselor at 2,4,8, and 12 weeks, placebo patch	14.0%	12	Yes
			115	Advice to quit, follow-up by counselor at 2,4,8, and 12 weeks, nicotine patch	21.0%	12	Yes
Taylor	1996	Smokers hospitalized over 36 hours	315	Meeting with nurse case manager, use of videotape, workbook, relaxation tape, NRT, and follow-up calls	31.0%	12	Yes
			313	Usual care	21.0%	12	Yes
Simon	1997	Smokers who underwent non-cardiac surgery	168	Counseling, videotape, self-help literature, NRT, 3 months phone follow-up	15.0%	12	Yes
			156	10 minute brief counseling, self-help literature	8.0%	12	Yes
Rigotti	1997	Smokers hospitalized over 48 hours, excluding intensive care, cognitively impaired	325	15 minute bedside counseling, self help literature, up to 3 weekly phone calls	8.1%	6	Yes
			325	Usual care	8.7%	6	Yes
Rosal	1998	Coronary patients	82	30 minute counseling session, one outpatient counseling visit, follow-up calls	49.0%	60	No
			78	10 minute advice to quit	40.0%	60	No
Lewis	1998	Smokers admitted > 24 hours, excluding drug or alcohol abusers, psychiatric patients, pregnant women, terminal illness, intensive care, major cardiac condition	61	Brief physician motivational message, pamphlet	4.9%	6	Yes
			62	Counseling, nicotine patch, telephone counseling	9.7%	6	Yes
			62	Counseling, placebo patch, telephone counseling	6.5%	6	Yes

### *Free-standing smoking cessation programs*

There are very few inpatient or residential programs designed specifically for smoking cessation. However, in Minnesota, both Hazelden and the Mayo Clinic have such programs. Between 1990 and 1997, almost 400 people were admitted to Hazelden's five-day residential smoking cessation program which uses a 12-step philosophy, cognitive behavioral therapy, stress management, massage, and acupuncture. About two-thirds of the clients were recovering from drug or alcohol addiction (Hazelden's primary focus). The facility reports that about 35% of clients were smoke-free at one-year follow-up.<sup>40</sup>

In 1988, the Mayo Clinic tested the feasibility of a 14-day inpatient program designed to treat nicotine dependence. Modeled after similar programs for drug users, the program combined behavioral, chemical-dependence, and transdermal NRT in a smoke-free environment. The subjects underwent follow-up for 10 weeks after departure and were contacted periodically thereafter. At one year, 29% of the 24 subjects were smoke-free.<sup>41</sup>

The Nicotine Dependence Center at the Mayo Clinic also provides a range of outpatient treatments. An evening group program consists of a series of six sessions, each of which includes an hour of group therapy and a one-hour lecture on specific related topics.<sup>42</sup> The relapse-prevention program consists of follow-up phone calls at one, three, and six months after initial consultation, eight mailed letters, and a one-year follow-up survey. Clients from 1988, the first year of the program, had a one-year quit rate of 20.3%.<sup>43</sup>

The American Cancer Society (ACS) and the American Lung Association (ALA) also conduct smoking cessation clinics. Lando<sup>44</sup> compared a program he designed with their programs in a randomized trial that took place in three Iowa locations. The ACS program consisted of an

orientation session plus four one-hour group sessions over a two-week period. Instructions to clinic leaders placed relatively more weight on individual situations than on group processes. There was no set target date for abstinence. The ALA clinic format consisted of an orientation session and seven additional 90- to 120-minute sessions over a seven-week period. Quit Day occurred at the third session, and the remaining sessions were focused upon maintenance and a healthy lifestyle. Lando's treatment consisted of 16 sessions (45 to 60 minutes each) over a nine-week period. The first three weeks were devoted to preparation for quitting, and the final six, to maintenance. The preparation technique involved switching brands on a 30-60-90 percent weekly reduction schedule. Lando also used an aversive smoke-holding procedure.<sup>45</sup>

Although differences in one-year point prevalence were not significant, there were significant differences in one-year sustained abstinence. Sustained abstinence for the ACS program was 12.08%, compared with 19.01% for the ALA program and 22.19% for the Lando program ( $p < 0.014$ ). In addition, significantly fewer clients from the ACS program made a quit attempt ( $p < 0.004$ ).

In sum, the few published articles on residential/inpatient smoking cessation programs did not meet our standards for rigor. Importantly, neither study included a control group. In addition, the Hazelden report did not confirm abstinence through biochemical means. Thus, we can not make a statement about the effectiveness of such programs. The only study we found of outpatient smoking cessation clinics was a randomized trial. Although this study did not have a pure control group, it does support recent meta-analysis results indicating that more intensive programs lead to increased success.

#### QUESTION 11. WHO IS MORE EFFECTIVE IN DELIVERING SMOKING CESSATION INTERVENTIONS?

We identified one systematic review that assessed nursing interventions specifically, and two meta-analyses that assessed the relative effectiveness of different providers. We also conducted our own meta-regression analysis focussing on the relative effectiveness of different providers.

In a systematic review of 14 studies specifically focusing on nursing interventions,<sup>32</sup> smoking cessation rates improved over usual care (odds ratio=1.43, 95% C.I.=1.24 to 1.66). Interventions included cessation advice, counseling, and psychological feedback.

A systematic review of 41 studies comparing nonmedical healthcare providers (social workers, counselors, psychologists), nonphysician medical care providers (pharmacists, nurses, dentists) and physician providers found no statistically significant differences in smoking cessation rates among patients who saw these various providers. The pooled odds ratio was 1.8% (95% C.I.=1.5 to 2.2) for nonmedical providers, 1.4 (95% C.I.=1.1 to 1.8) for nonphysician medical providers, and 1.5 (95% C.I.=1.2 to 1.9) for physicians.<sup>17</sup> However, interventions using multiple providers were found to be more effective than interventions using a single provider (pooled odds ratio=2.8, 95% C.I.=2.6 to 5.6).

In the recent Public Health Service clinical practice guideline the difference between physicians and non-physician clinicians approached statistical significance. The odds-ratios are presented in the table below.



**Table 8. Efficacy of Interventions Delivered by Various Types of Clinicians**

<b>Type of Clinician</b>	<b>Estimated Odds Ratio</b>	<b>95% C.I.</b>	<b>Estimated Abstinence Rate</b>	<b>95% C.I.</b>
No clinician	1.0		10.2	
Self-Help	1.1	0.9-1.3	10.9	9.1-12.7
Nonphysician clinician	1.7	1.3-2.1	15.8	12.8-18.8
Physician clinician	2.2	1.5-3.2	19.9	13.7-26.2

We conducted a meta-regression containing 56 arms comparing an intervention with a control group. The results are given in Table 9.

**Table 9. Meta-regression Results by Provider**

<b>Provider</b>	<b>Adjusted Odds Ratio</b>	<b>95% C.I.</b>
Physician	3.02	2.62-3.48
Psychiatrist/psychologist	2.68	1.79-4.00
Nurse	2.38	1.87-3.03
Counselor	1.87	1.35-2.61
Unknown	1.41	1.09-1.83
Other (self-help, etc)	1.37	1.15-1.65

The trend indicates that physicians are the most effective intervention providers, compared with control, followed by psychiatrists/psychologists, then nurses. Physicians had a statistically significant advantage over lay counselors, self-help, and interventions where provider was unknown. Interventions using psychiatrists/psychologists and nurses were shown to be significantly more effective than self-help or interventions with unknown provider type.

In summary, the data support that many types of providers are effective. In two of three comparative meta-analyses, physician providers compared to non-physician providers had a higher estimated odds ratio of effectiveness, and in one synthesis this difference was statistically significant.

#### QUESTION 12. DO CERTAIN INTERVENTIONS WORK BETTER FOR SPECIAL POPULATIONS?

##### *Hispanics / Latinos*

We found a single controlled trial of smoking cessation interventions designed specifically for Latinos. In Queens, New York, Nevid and Javier<sup>46</sup> compared a culturally specific multicomponent intervention with a low-intensity, enhanced self-help control. The intervention group (N=78) met weekly to watch videos containing culturally specific smoking-related vignettes. Members of each group were of the same gender. The sessions followed a staging model in which exposure to motivation enhancement exercises was followed by relapse-prevention training in later sessions. The control group (N=75) attended an introductory session and received supportive follow-up telephone calls. Both intervention and control groups were given the ALA smoking cessation manual, *Freedom from Smoking in 20 Days* (in both English and Spanish), as well as a Spanish-language help booklet, *Guia para Dejar de Fumar*.

Unfortunately, only two participants (one in the control group, one in the intervention) demonstrated cotinine-validated abstinence at both post-treatment and 12-month follow-up. Thus, the benefits of this particular culturally specific, multicomponent intervention for Latinos/Latinas are questionable and certainly do not persist over time.

### *African Americans*

Although the vast majority of smoking studies consist primarily of Caucasian subjects, several studies have evaluated smoking cessation interventions designed specifically for African Americans. The most recent studies are described below.

Ahluwalia and colleagues<sup>47</sup> conducted a double-blind, randomized controlled trial at a hospital outpatient program for inner-city African Americans. The multifaceted intervention included brief counseling, a culturally appropriate cessation guide written at sixth-grade level, and either a nicotine patch or a placebo patch. In addition, patients were reimbursed for transportation costs. The six-month self-reported quit rate was 17.1% for the nicotine patch group and 11.7% for the placebo patch group ( $p < .08$ ).

Fisher<sup>48</sup> studied a community intervention in low-income African American neighborhoods in St. Louis. The intervention included smoking cessation classes, billboards, a gospel fest, and door-to-door distribution of self-help materials. Over two years, smoking prevalence decreased from 34% to 27% in program neighborhoods, and from 34% to 33% in control neighborhoods in Kansas City.

Schorling and colleagues<sup>49</sup> studied a church-based intervention in rural Virginia which combined one-on-one counseling with self-help materials and communitywide activities. The intervention was implemented throughout one county, while a similar county served as a control. There was a significant change in subjects' stages of change in the intervention county compared with the stages of change in the control county. Although the smoking cessation rate was higher in the intervention county, the difference was not statistically significant.

In the 1980's, the Harlem Health Connection developed and tested a culturally sensitive self-help smoking cessation program<sup>50</sup> based on Prochaska's stages of change.<sup>51</sup> Members of the intervention group received a culturally sensitive cessation guide written at fifth-grade level, a cessation video featuring African American historical figures, and a telephone booster call. The control group received health education materials not directly addressing smoking. There was no significant difference in quit rates between the intervention group and the control group at six-month follow-up.

Goldberg<sup>52</sup> designed an intervention based on the stages of change which involved training medical residents to provide brief counseling to patients. The intervention took place in the outpatient section of Chicago's Cook County Hospital, where over 90% of the patients are African American. The trained residents saw patients in the intervention group, while residents who did not undergo the training saw the control group. Although the intervention group moved ahead in stages of change, the difference in quit rates between the groups was not statistically significant.

In summary, one of the five studies targeted toward African American populations showed statistically significant improvements in smoking cessation compared to control. No studies have been reported that demonstrate reduced or enhanced effectiveness of generic smoking cessation interventions among different ethnic/racial groups. Thus, we encourage studies on generic interventions to publish results stratified by these groups. In addition, more research on the effectiveness of targeted versus generic interventions is needed.

### QUESTION 13 & 14. WHAT ARE THE COSTS AND COST EFFECTIVENESS OF INTERVENTIONS?

This section will discuss the cost and cost-effectiveness of different interventions studied in this review, including counseling, self-help and mass media. It is important to note that medications are sometimes combined with these interventions. Few articles except for those specifically on cost-effectiveness detail costs. Table 10 lists the average wholesale cost per dose and cost per day for these medications.<sup>33</sup>

**Table 10. Costs of Smoking Cessation Medications  
(average wholesale price)**

<b>Medication</b>	<b>Cost per dose</b>	<b>Cost per day</b>
Nicotine patch	\$3 each	\$3
Nicotine inhaler	\$1/ 10mg	\$1.50
OTC Nicotine gum	\$0.50/ piece	\$5
Bupropion	\$1.40/ 150 mg pill	\$2.80
Clonidine*	\$0.25/ 0.2mg pill	\$0.50

\* not FDA approved for smoking cessation

#### *Which interventions are most cost-effective?*

The available evidence suggests that smoking cessation interventions are highly cost-effective when compared with other medical treatments and prevention programs.<sup>18, 34</sup> The widely held view of smoking cessation as the “gold standard” of healthcare cost-effectiveness is underscored by the fact that even the least cost-effective smoking intervention — the use of nicotine gum as an adjunct to physician counseling — is estimated to cost less than half the median cost per life-year saved of nearly 600 life-saving interventions.<sup>35</sup>

We reviewed 15 published studies examining the cost-effectiveness (C/E) of various smoking cessation programs and three review articles. Eight of the cost-effectiveness analyses (CEA)

were medical practice-based and seven were community-based interventions. In general, community-based programs tended to be less cost-effective than practice-based interventions. Further, practice-based interventions generally applied more rigorous methodologies such as randomized clinical trials. All of the studies discussed below and outlined in Table 11 examined adult smokers, yet none solely targeted the elderly.

**Table 11. Summary of Cost-effectiveness of Smoking Cessation Interventions  
in 1999 dollars**

Interventions	Cost effectiveness*	Characteristics	Reference
<i>Medical practice-based interventions</i>			
Counseling only	\$317	Brief advice in U.K. (3 minutes)	Parrott, 1998 <sup>53</sup>
Counseling and self-help material	\$403	Brief advice in U.K. (4 minutes)	Parrot, 1998 <sup>53</sup>
	\$5,928	Minimal individual (3 minutes)	Cromwell, 1997 <sup>27</sup>
	\$4,696	Brief individual (7 minutes)	“ “
	\$2,237	Full individual (15 minutes)	“ “
	\$2,690	Intensive individual	“ “
	\$1,635	Intensive group	“ “
Counseling, self-help material and NRT	\$490 (patch)	Brief advice in U.K. (7 minutes)	Parrott, 1998 <sup>53</sup>
	\$3,551 (patch)	Minimal individual (6 minutes)	Cromwell, 1997 <sup>27</sup>
	\$6,707 (gum)	Minimal individual (6 minutes)	“ “
Adding NRT to physician counseling	\$686 ~ \$1,354 (patch)	Under Age 35 up to 65 years in U.K.	Stapleton, 1999 <sup>54</sup>
	\$1,963 ~ \$2,603 (patch)	Men age 35-64	Wasley, 1997 <sup>55</sup>
	\$3,224 (patch)	Men age 65-69	“ “
	\$3,323 ~ \$4,000	Women age 35-64	“ “
	\$5,069 (patch)	Women age 65-69	“ “
	\$4,799 ~ \$8,808 / QALYS (patch)	Men age 25-64	Fiscella, 1996 <sup>56</sup>
	\$11,963 / QALYS (patch)	Men age 65-69	“ “
	\$5,417 ~ \$6,851 / QALYS (patch)	Women age 25-64	“ “
	\$7,634 / QALYS (patch)	Women age 65-69	“ “
	\$6,368 ~ \$8,085 (gum)	Men age 35-64	Oster, 1986 <sup>57</sup>
	\$10,010 (gum)	Men age 65-69	“ “
	\$10,652 ~ \$13,929 (gum)	Women age 35-64	“ “
	\$14,400 (gum)	Women age 65-69	“ “
Hospital programs	\$254	Nurse-managed program for acute MI patients	Krumholz, 1993 <sup>58</sup>
	\$1,901 - \$8,368	Hospital-based (counseling, video, self-help, follow-up phone calls)	Meenan, 1998 <sup>59</sup>
Specialist clinics	\$ 465	Specialist service in addition to physician counseling and NRT (U.K.)	Parrott, 1998 <sup>53</sup>
	\$7,872	Mayo Clinic with a variety of intervention approaches	Croghan, 1997 <sup>42</sup>

**Table 11. Summary of Cost-effectiveness of Smoking Cessation Interventions in 1999 dollars (continued)**

Interventions	Cost effectiveness*	Characteristics	Reference
<i>Community-based interventions</i>			
Self-help / quit contests	\$264/ quitter	1 yr	Altman, 1987 <sup>60</sup>
	\$909-\$2,113/ quitter	1 yr (1979 dollars)	Davis, 1984 <sup>61</sup>
Mass media	\$596 - \$1,286	Television spots and phone helpline (U.K.)	Ratcliffe, 1997 <sup>62</sup>
	\$1,538-\$1,721	(Sweden)	“ “
	\$55/ quitter	At 1 yr (television spots were free)	Danaher, 1984 <sup>63</sup>
Workplace programs	\$2.05/\$1 cost-benefit ratio	18 months - Health promotion program.	Bertera, 1990 <sup>64</sup>
State initiatives	CA: decline of 3.9 packs/capita/yr	Effect of 8 advertising strategies to prevent smoking in CA and MA.	Goldman, 1998 <sup>65</sup>
	MA: decline of 0.5 packs/capita/yr		“ “

\* Cost-effectiveness expressed as cost per life year saved in 1999 dollars in both the table and the text, unless otherwise noted.

### *Medical Practice-Based Interventions*

Before the advent of NRT in the 1980s, smoking cessation programs largely consisted of self-help guides and physician exhortations to quit.<sup>18, 34</sup> Yet once NRT was widely shown to increase cessation rates, it became a critical component of most smoking interventions. Recent studies by Cromwell et al.<sup>27</sup> and Parrott et al.<sup>53</sup> examined the cost-effectiveness of adding self-help and nicotine replacement therapy to physician counseling. Cromwell and colleagues analyzed 15 interventions based on clinical practice guidelines outlined by AHRQ (formerly AHCPR).<sup>17</sup> The interventions included five counseling options (minimal, brief, full, individual intensive, and group intensive), either alone or in conjunction with two types of nicotine replacement therapy (transdermal nicotine patch or nicotine gum). Outcome measures included cost per quitter, cost per life-year saved, and cost per quality-adjusted life-year (QALY), and C/E ratios were computed relative to use of self-help materials only. Cromwell et al. estimated that the cost per



life year saved ranged from \$1,635 to \$6,707 across the various interventions. Furthermore, more intensive counseling and counseling combined with a nicotine patch were more cost-effective than other counseling options or counseling with nicotine gum.

Parrott et al.<sup>53</sup> examined similar interventions, yet reached somewhat different conclusions. Parrott and colleagues estimated the cost per life year saved due to the interventions was less than \$500. In addition, counseling in conjunction with a nicotine patch cost more per life-year saved than counseling alone or counseling with self-help materials. This finding is consistent with Warner's observation that costs increase faster than effectiveness. It is difficult to compare findings across studies because they rely on different methodologies, patient populations, and health care environments (U.K. vs U.S.). For example, the studies by Parrott and Cromwell assumed widely different relapse rates, counseling time, and required physician wage rates. Further, they evaluated the effectiveness of the interventions against somewhat different controls.

Four additional studies estimated the cost-effectiveness of adding pharmacotherapy to provider counseling. Three of the studies estimated the marginal impact of nicotine patches,<sup>54-56</sup> while Oster et al.<sup>57</sup> examined nicotine gum as an adjunct to counseling. Oster et al. found that nicotine gum in combination with physician counseling cost \$6400 to \$14400 per life year saved above physician counseling only, depending on the participants age and gender. This compares favorably with other medical interventions, but based on current estimates, is less cost-effective than nicotine patches and counseling. The three "patch" studies yielded C/E ratios ranging from roughly \$700 to \$7000 per life year saved. Stapleton et al.<sup>54</sup> found more favorable C/E due to lower medical costs in the U.K. than the U.S. and greater patient cost-sharing of NRT. Fiscella and Franks<sup>56</sup> reported the least favorable effect of nicotine patches, largely because they assumed

higher use of pharmacotherapy per smoker and lower effectiveness rates compared to Wasley et al.<sup>55</sup> All four studies of NRT provided age-specific C/E ratios, and three of the four found that cost-effectiveness declined modestly with age.

Other practice-based smoking cessation interventions included hospital-based programs and specialist clinics. Because these programs were often operated by nonphysician clinicians (e.g., nurses, counselors), costs per-minute of counseling were substantially lower than physician-based approaches. Moreover, they typically involved more intensive treatment and thus achieved higher quit rates, especially among smokers who had failed in less-intensive treatments. The principal limitation of these types of specialized programs is that they fail to reach the vast majority of smokers.

### *Community-Based Interventions*

Several researchers have examined the effectiveness of advertising and mass media campaigns that encourage smokers to quit or discourage youth from starting to smoke.<sup>62, 63, 65</sup> Community-based interventions typically reach a far broader audience of smokers and nonsmokers than practice-based programs. For example, a brief mass-media campaign in Scotland resulted in over 82,000 calls to a telephone quitline, and was modestly successful in increasing quit rates.<sup>62</sup> Another community-based study by Altman et al.<sup>60</sup> compared the effectiveness of a smoking cessation class, an incentive-based quit contest, and a self-help smoking kit. They found the smoking cessation class was the most effective in reducing smoking prevalence, while the self-help kit was the most cost-effective.

A recent meta-analysis of anti-smoking advertisements indicates that the content and delivery of mass media campaigns have direct impact on participation rates and effectiveness. Goldman et

al.<sup>65</sup> found that more aggressive anti-smoking campaigns are more effective in reducing tobacco consumption. Further, ads that emphasize industry manipulation and secondhand smoke were believed to be the most effective in a review of evidence from 186 focus groups.

Studies of smoking cessation in the workplace are often part of larger programs concerned with health promotion and prevention. These studies differ from most smoking cessation programs in that the principal outcome measure is workloss or disability days rather than quit rates or costs per quitter. Bertera<sup>64</sup> evaluated a large, multi-site health promotion program using a pre- and post-control group design. Disability days declined more than 8 percentage points over two years for hourly employees who participated in health promotion classes and self-help programs -- including smoking cessation -- compared to the control groups. While findings from workplace-based programs appear to be highly effective, it is difficult to assess the impact of specific smoking interventions when they are part of broader health promotion programs.

All of the studies reviewed saved life-years at a cost as low as several hundred dollars to a high of \$14,000, with a median value of about \$5,000 per life year saved. These findings are well below the estimates of most other health interventions. The principal shortcoming of this literature is a lack of evidence on the effectiveness of smoking cessation programs for specific patient subgroups -- such as the elderly -- and their preferences for specific interventions. As Warner<sup>34</sup> noted, different interventions are effective for different people. A resource-intensive treatment may be cost effective for smokers who do not respond to less-intensive programs, but may not be successful for smokers attempting to quit for the first time. Further investigation is needed to determine the cost-effectiveness of various smoking cessation interventions on specific patient populations.

## **LIMITATIONS OF THIS REVIEW**

The primary limitation of this systematic review—a limitation that is common to all such reviews—is the quantity and quality of the original studies. Even more so than in reviews of single therapies (e.g., coronary revascularization for coronary artery disease, pharmaceutical therapy for rheumatoid arthritis), the studies presented here are extremely heterogeneous in terms of both the interventions tested and the specific populations or health care systems studied. Furthermore, many of the study-level variables are highly idiosyncratic and intercorrelated (e.g., a study of patient education with nurses may also be a study of NRT among low-income African Americans). This correlation between intervention-level variables and population makes the assessment of the effect of the individual components challenging.

We gave equal importance to all studies that met our minimum criteria. We made no attempt to give greater importance to those that had better design and characteristics that have been postulated to produce more valid results, because for these types of studies, there is a lack of empirical evidence of the relationship between study characteristics and bias.

In addition, several studies randomized by provider or clinic. Because the majority of these studies did not correct for the potential clustering of patients within one of these larger units, they tended to underestimate the variance in the estimate of the effect of the intervention.

Finally, this study assumes that interventions will achieve equal success when targeted toward adults 65 years of age or older. We were not able to empirically test this assumption because we had insufficient data.

## CONCLUSIONS

1. Individual, telephone, and group counseling are all effective, with individual counseling being possibly most effective.
2. There is consistent evidence from multiple analyses that greater intensity of counseling yields higher smoking cessation rates.
3. Nicotine replacement therapy (NRT), clonidine, and bupropion are all effective as pharmacotherapy for smoking cessation, although clonidine is not approved by the FDA for this use.
4. Patients visiting physicians trained in smoking cessation had higher cessation rates than those visiting untrained physicians.
5. Health insurance benefits of 100% for both counseling and NRT produced the greatest number of quitters in a population.
6. There is good evidence that both medical and non-medical providers are effective at delivering smoking cessation services, but conflicting evidence about the relative degree of effectiveness between provider types.
7. Interventions with follow-up calls or visits are more effective than those without.
8. There are insufficient data to support or refute variations on smoking cessation interventions among special populations.

## **RECOMMENDATIONS**

Recommendations based on the evidence were formulated by a panel of experts on smoking cessation, health services research, medicine, and behavior change.

1. Smoking cessation interventions should be tested as a Medicare benefit.
2. Any demonstration project should include pharmacotherapy, physician visit, and/or telephone hotline. Group counseling should not be required, as most older smokers will avoid groups.
3. Primary care practitioners participating in smoking cessation demonstrations should be offered and encouraged to have training in this area.
4. There is no evidence that paying providers for outcomes will work, and there is considerable evidence that it will not. However, providers should be held accountable for their performance in accordance with the AHRQ guidelines. The five As (ask, advise, assess, assist, and arrange) should be documented in provider records.
5. As in any demonstration project, sufficient numbers of minorities and women should be included.

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